US009409019B2

(12) **United States Patent**
Walker et al.

(10) **Patent No.: US 9,409,019 B2**
(45) **Date of Patent: Aug. 9, 2016**

(54) **LINKED AREA PARAMETER ADJUSTMENT FOR SPINAL CORD STIMULATION AND ASSOCIATED SYSTEMS AND METHODS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/617,745**

(22) Filed: **Feb. 9, 2015**

(65) **Prior Publication Data**

US 2015/0217113 A1 Aug. 6, 2015

Related U.S. Application Data

(63) Continuation of application No. 14/226,644, filed on Mar. 26, 2014, now Pat. No. 9,002,461, which is a continuation of application No. 13/914,494, filed on Jun. 10, 2013, now Pat. No. 8,712,535, which is a continuation of application No. 12/510,930, filed on Jul. 28, 2009, now Pat. No. 8,498,710.

(51) **Int. Cl.**

A61N 1/00	(2006.01)
A61N 1/36	(2006.01)
A61N 1/05	(2006.01)

(52) **U.S. Cl.**

CPC ***A61N 1/36071*** (2013.01); ***A61N 1/0551*** (2013.01)

(58) **Field of Classification Search**

USPC 607/2, 46, 116

See application file for complete search history.

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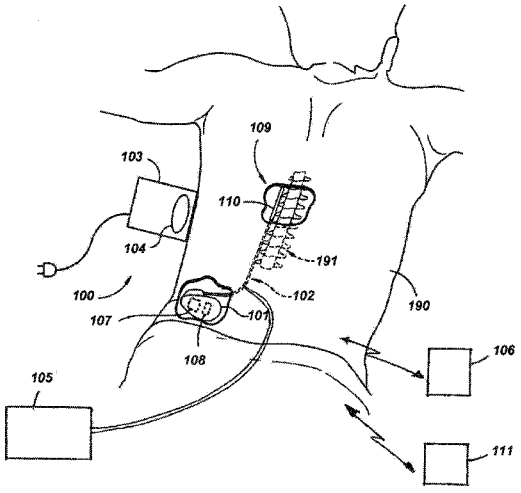
(57) **ABSTRACT**

Systems and methods for managing pain in a patient using an electrical waveform that link the modulation of a waveform parameter for different areas of a patient. One embodiment in a system for managing pain in a patient comprises an electric device configured to be implanted into the patient and including a plurality of electrodes having at least a first electrode associated with a first area of the patient and a second electrode associated with a second area of the patient. The system further includes an implantable device configured to be coupled to the electrode device and having a computer-operable medium programmed to change the waveform parameter applied to the first electrode and automatically set the waveform parameter applied to the second electrode based on a relationship between a first therapy range and a second therapy range of the waveform parameter.

34 Claims, 19 Drawing Sheets



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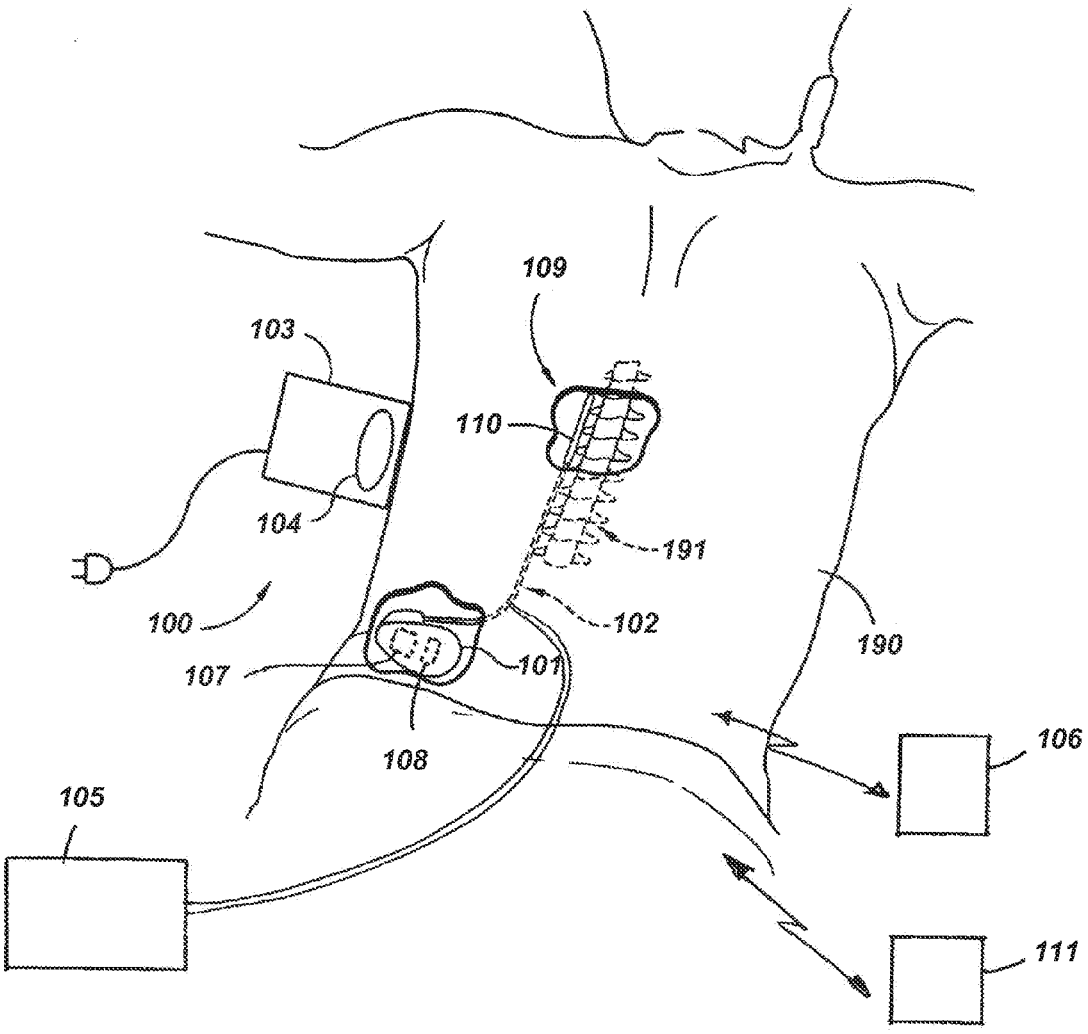

FIG. 1A

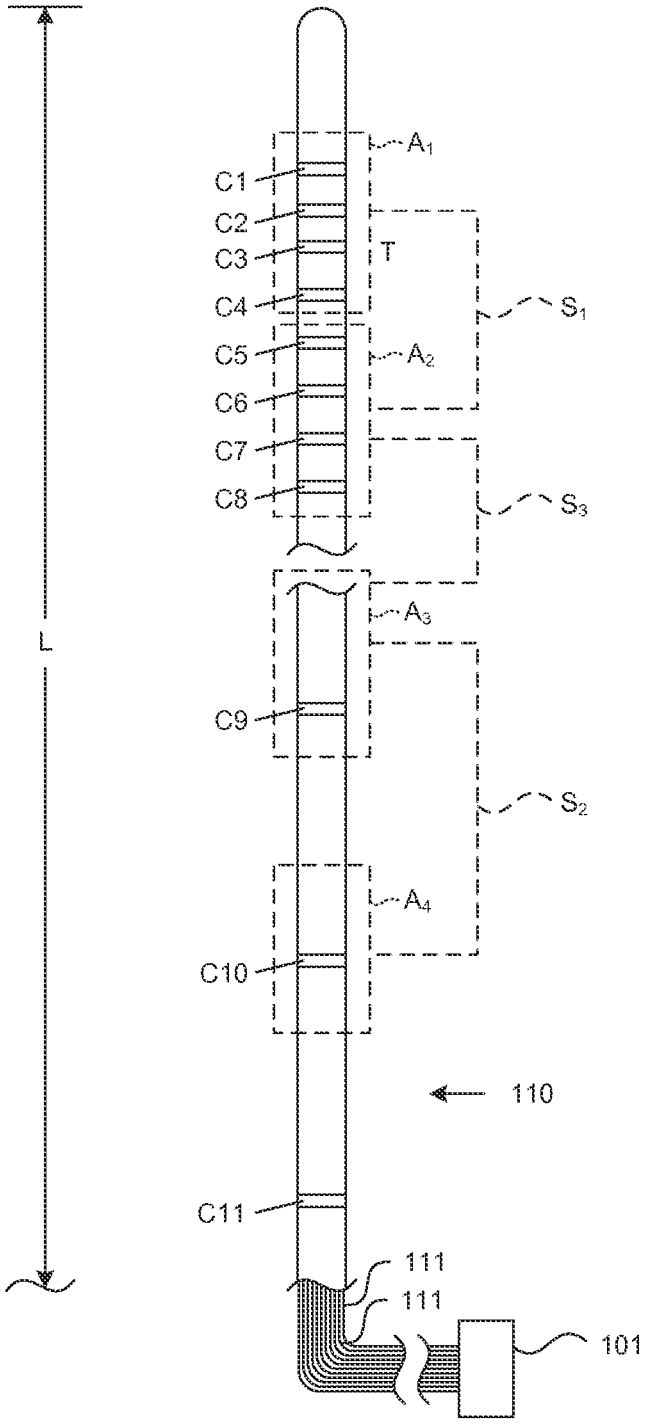
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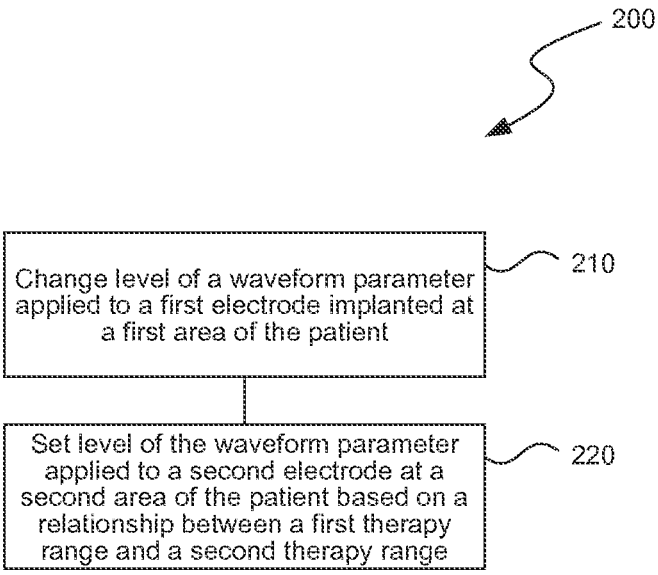
FIG. 1B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Change level of a waveform parameter applied to a first electrode implanted at a first area of the patient
210
Set level of the waveform parameter applied to a second electrode at a second area of the patient based on a relationship between a first therapy range and a second therapy range
220

FIG. 2

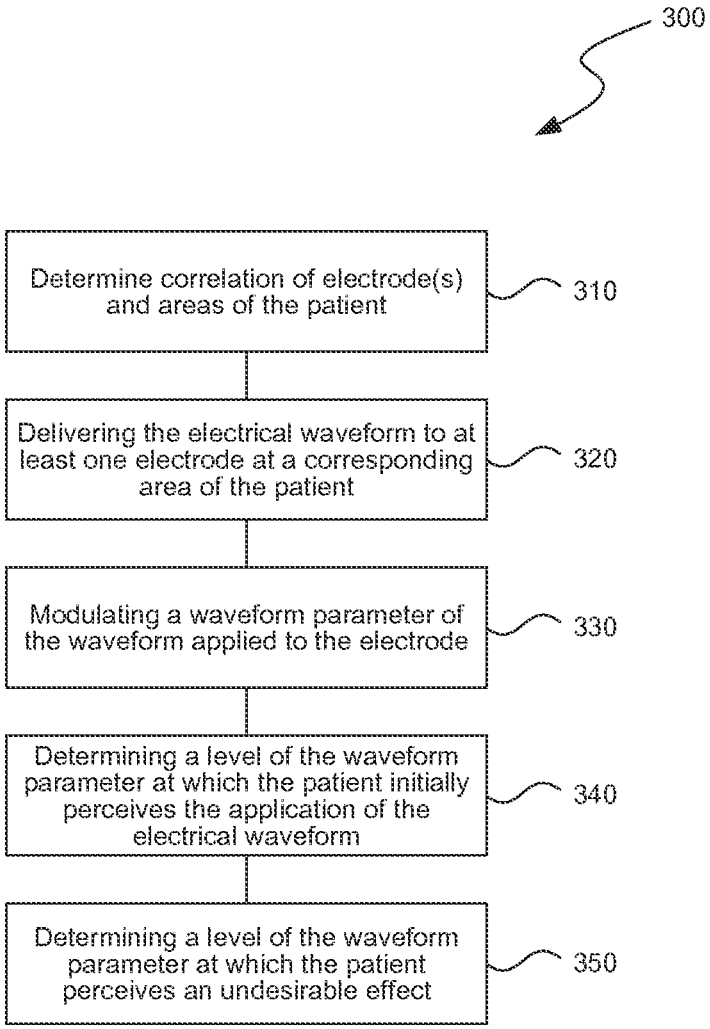
300
Determine correlation of electrode(s) and areas of the patient
310
Delivering the electrical waveform to at least one electrode at a corresponding area of the patient
320
Modulating a waveform parameter of the waveform applied to the electrode
330
Determining a level of the waveform parameter at which the patient initially perceives the application of the electrical waveform
340
Determining a level of the waveform parameter at which the patient perceives an undesirable effect
350

FIG. 3A

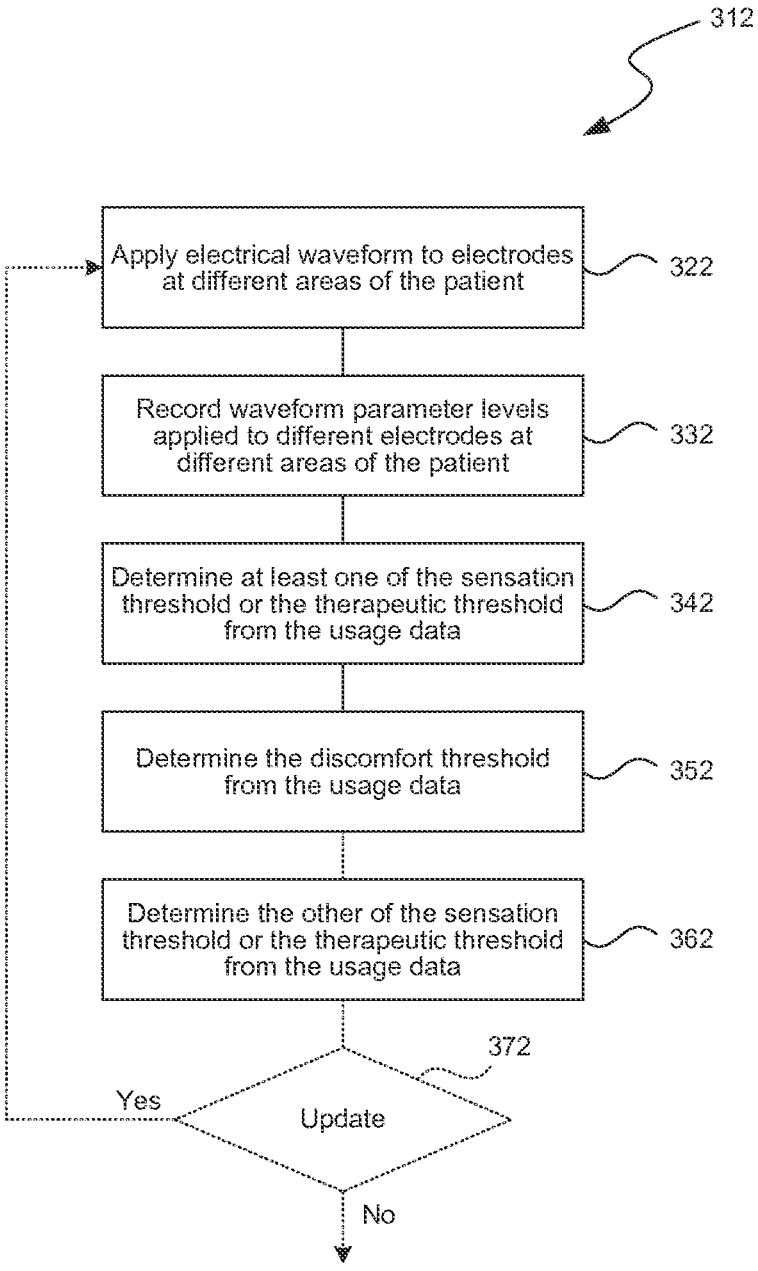
312
Apply electrical waveform to electrodes at different areas of the patient
322
Record waveform parameter levels applied to different electrodes at different areas of the patient
332
Determine at least one of the sensation threshold or the therapeutic threshold from the usage data
342
Determine the discomfort threshold from the usage data
352
Determine the other of the sensation threshold or the therapeutic threshold from the usage data
362
372
Update
Yes
No

FIG. 3B

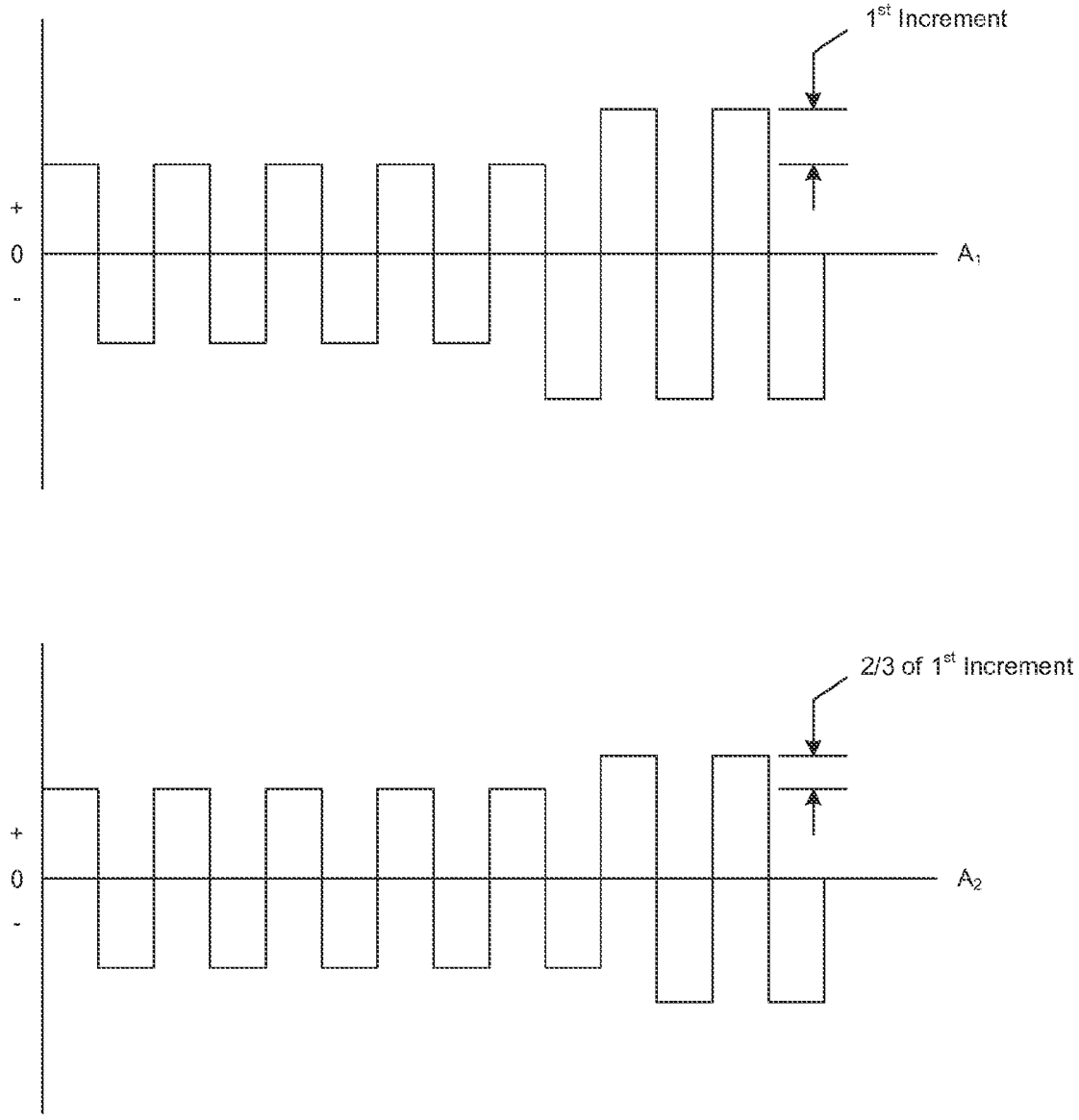

FIG. 4

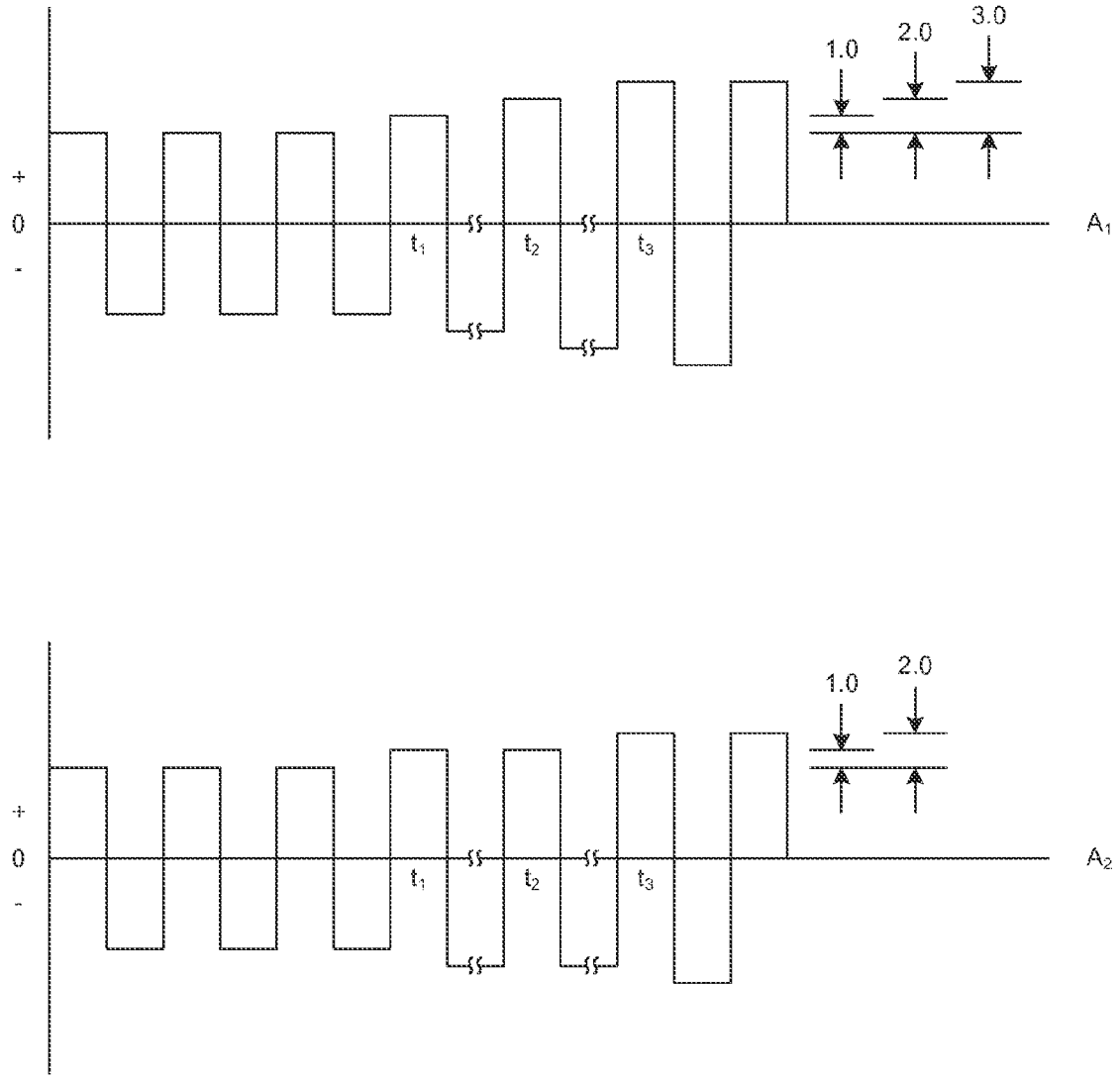

FIG. 5

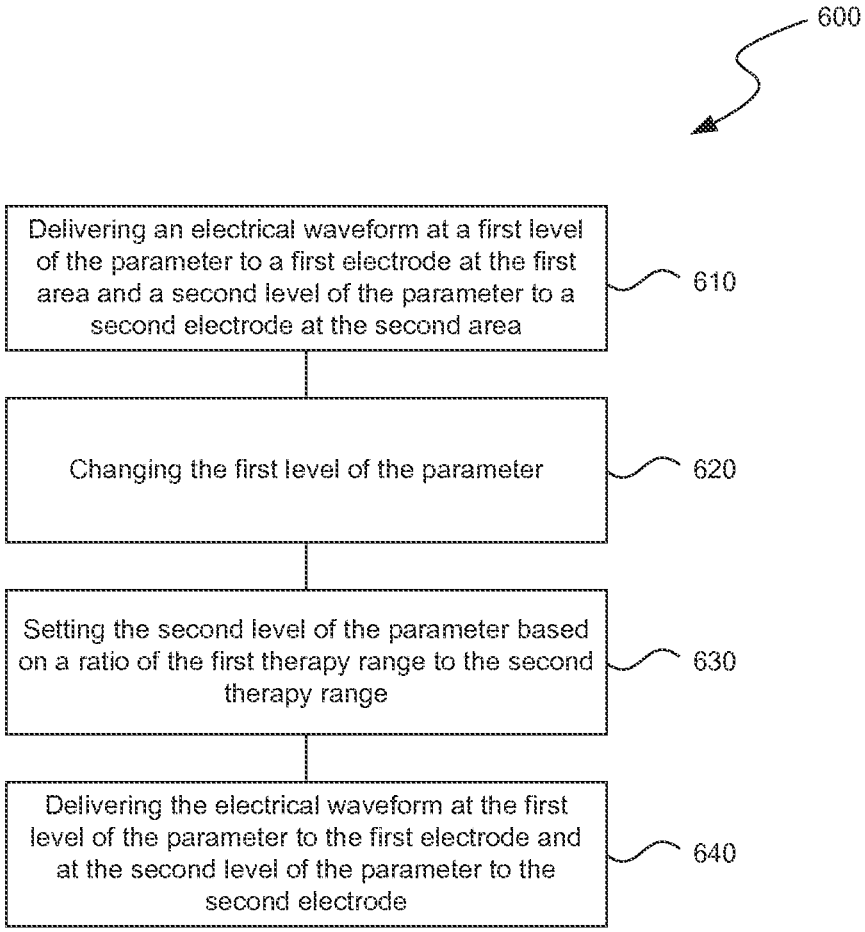
600
Delivering an electrical waveform at a first level of the parameter to a first electrode at the first area and a second level of the parameter to a second electrode at the second area
610
Changing the first level of the parameter
620
Setting the second level of the parameter based on a ratio of the first therapy range to the second therapy range
630
Delivering the electrical waveform at the first level of the parameter to the first electrode and at the second level of the parameter to the second electrode
640

FIG. 6

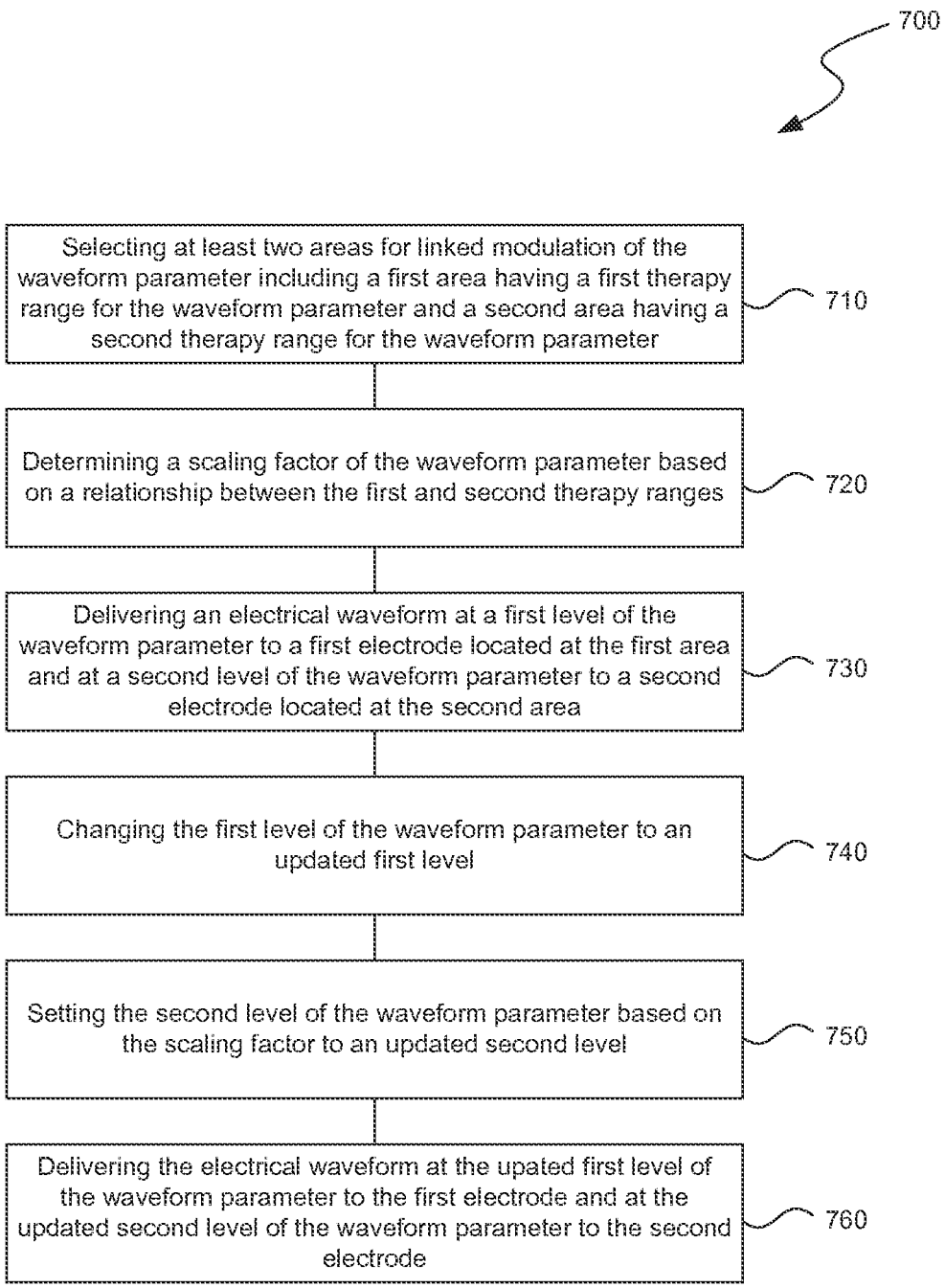
700
Selecting at least two areas for linked modulation of the waveform parameter including a first area having a first therapy range for the waveform parameter and a second area having a second therapy range for the waveform parameter
710
Determining a scaling factor of the waveform parameter based on a relationship between the first and second therapy ranges
720
Delivering an electrical waveform at a first level of the waveform parameter to a first electrode located at the first area and at a second level of the waveform parameter to a second electrode located at the second area
730
Changing the first level of the waveform parameter to an updated first level
740
Setting the second level of the waveform parameter based on the scaling factor to an updated second level
750
Delivering the electrical waveform at the upated first level of the waveform parameter to the first electrode and at the updated second level of the waveform parameter to the second electrode
760

FIG. 7

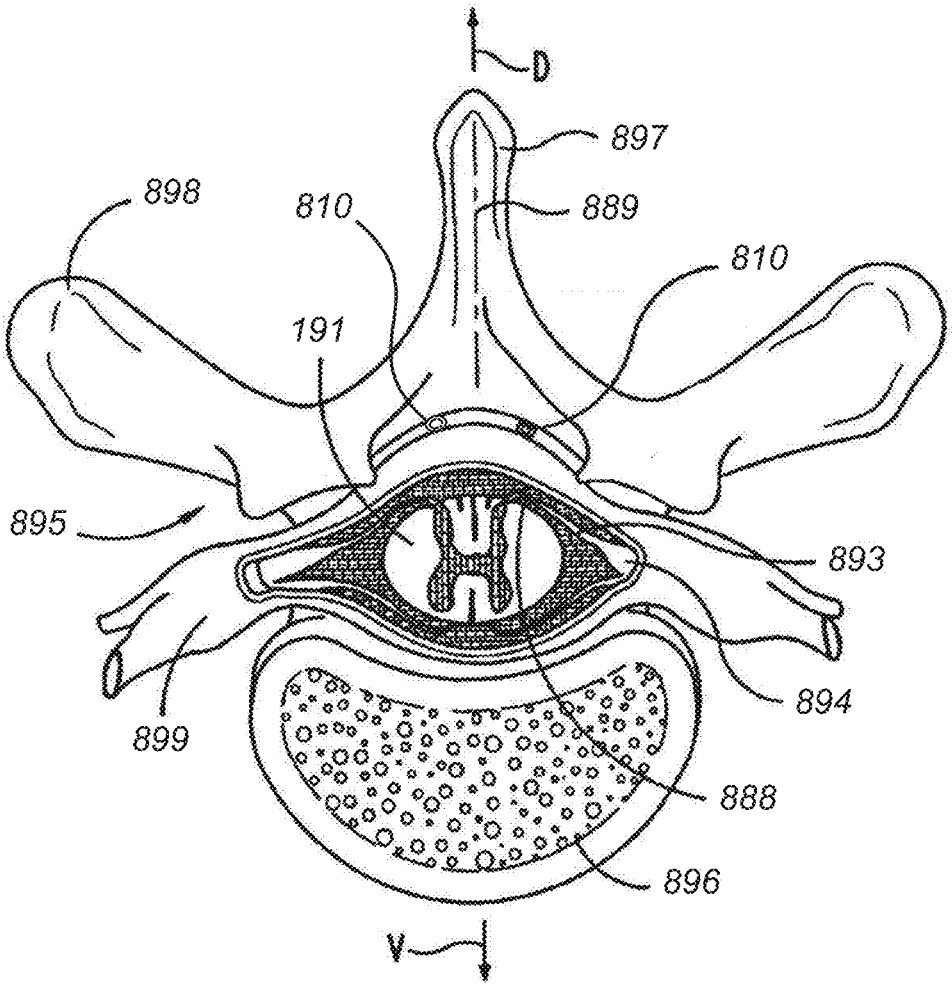

FIG. 8

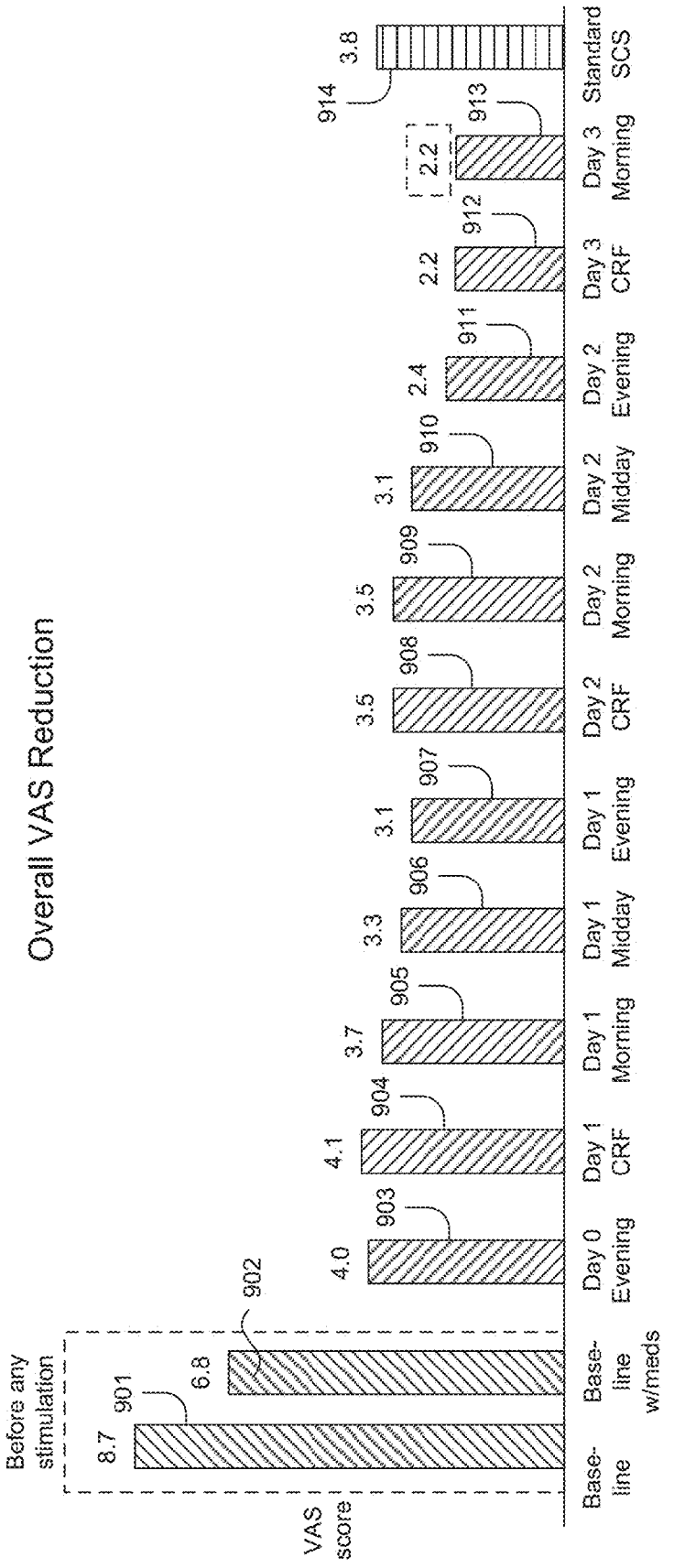
Overall VAS Reduction
VAS score
Before any stimulation
8.7
901
6.8
902
4.0
903
4.1
904
3.7
905
3.3
906
3.1
907
3.5
908
3.5
909
3.1
910
2.4
911
2.2
912
2.2
913
914
3.8
Base-line
Base-line w/meds
Day 0 Evening
Day 1 CRF
Day 1 Morning
Day 1 Midday
Day 1 Evening
Day 2 CRF
Day 2 Morning
Day 2 Midday
Day 2 Evening
Day 3 CRF
Day 3 Morning
Standard SCS

FIG. 9

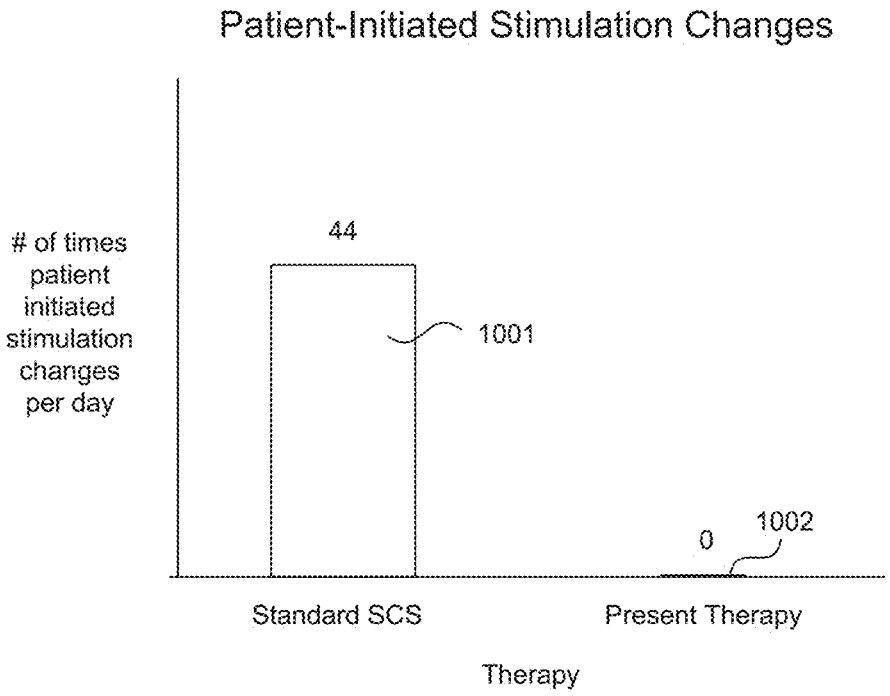
Patient-Initiated Stimulation Changes
# of times patient initiated stimulation changes per day
44
1001
0
1002
Standard SCS
Present Therapy
Therapy

FIG. 10

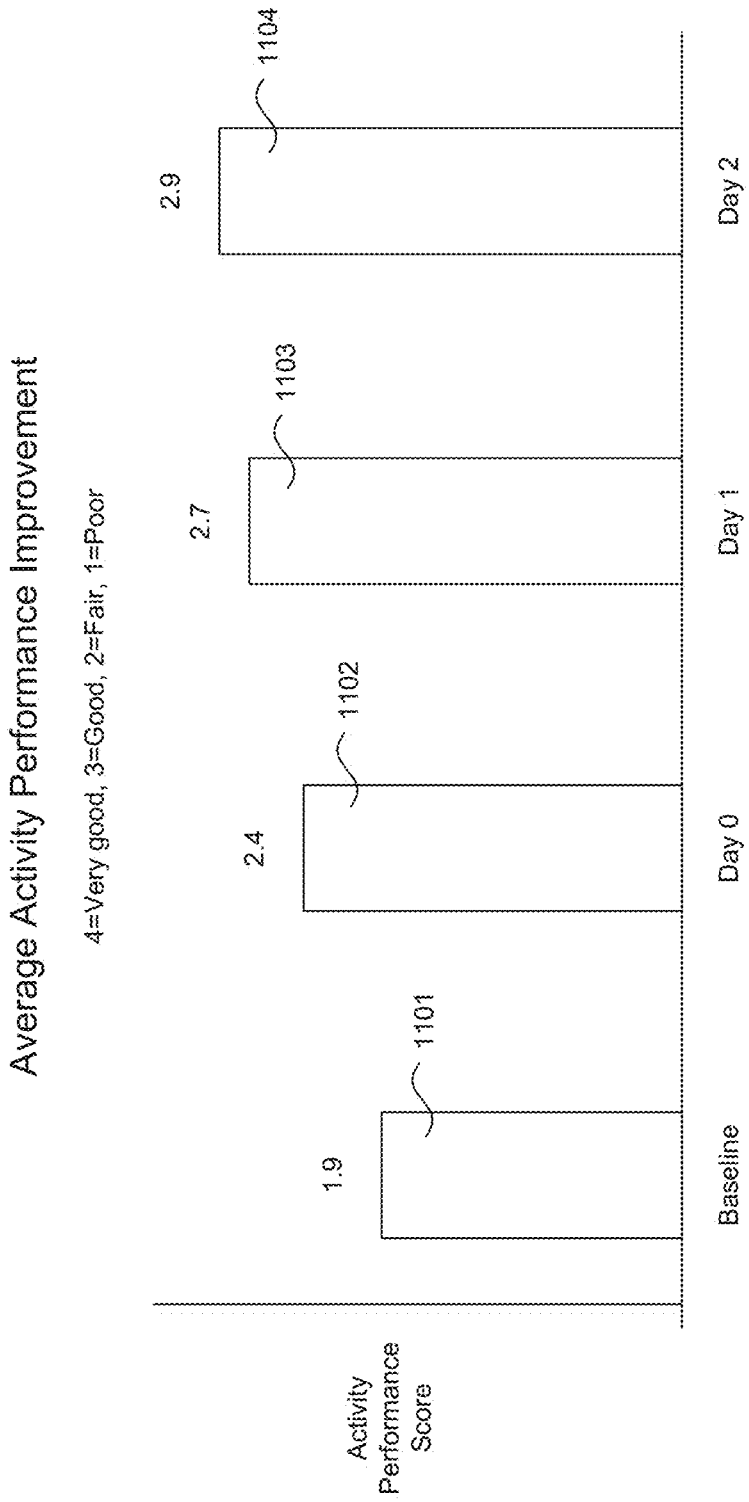
Average Activity Performance Improvement
4=Very good, 3=Good, 2=Fair, 1=Poor
Activity Performance Score
1.9
1101
Baseline
2.4
1102
Day 0
2.7
1103
Day 1
2.9
1104
Day 2
Time

FIG. 11

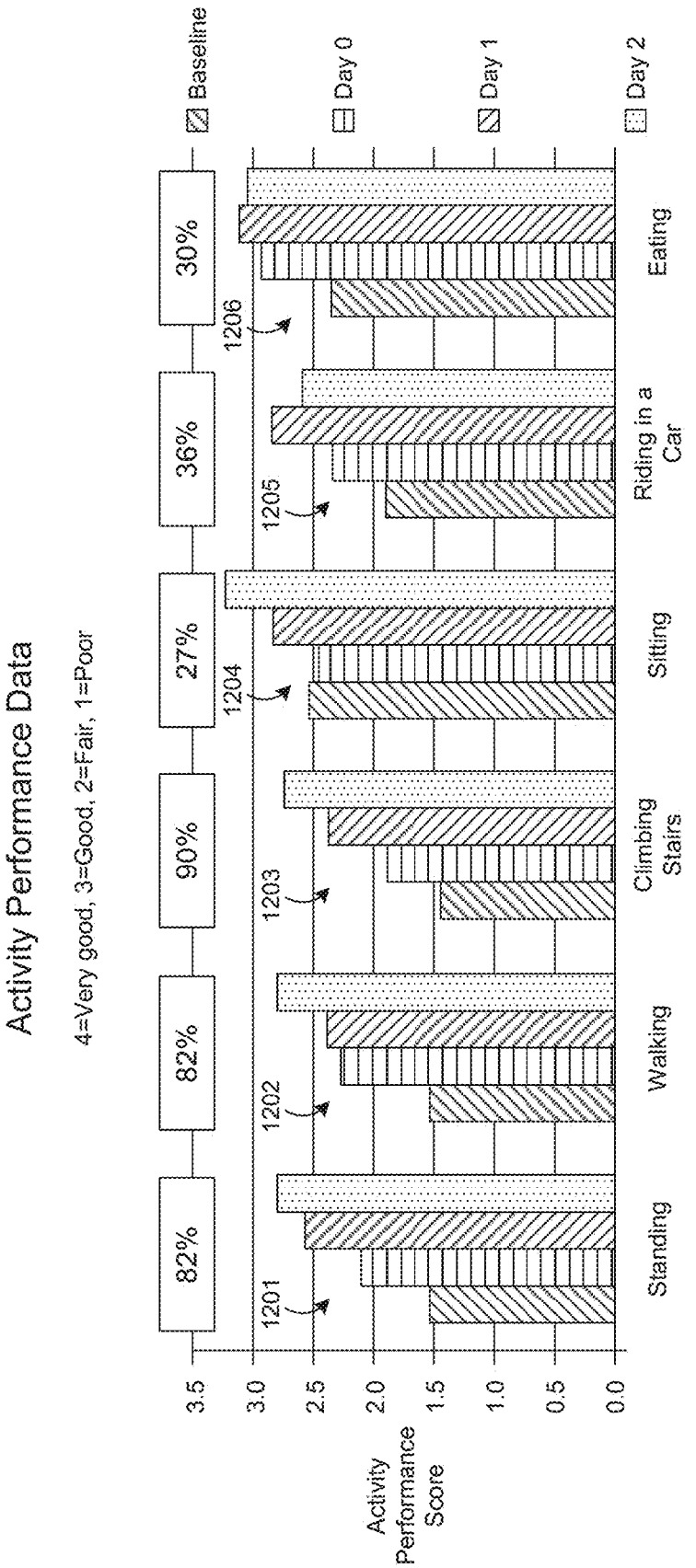
Activity Performance Data
4=Very good, 3=Good, 2=Fair, 1=Poor
Baseline
Day 0
Day 1
Day 2
82%
82%
90%
27%
36%
30%
1201
1202
1203
1204
1205
1206
Standing
Walking
Climbing Stairs
Sitting
Riding in a Car
Eating
Activity
Activity Performance Score
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0

FIG. 12

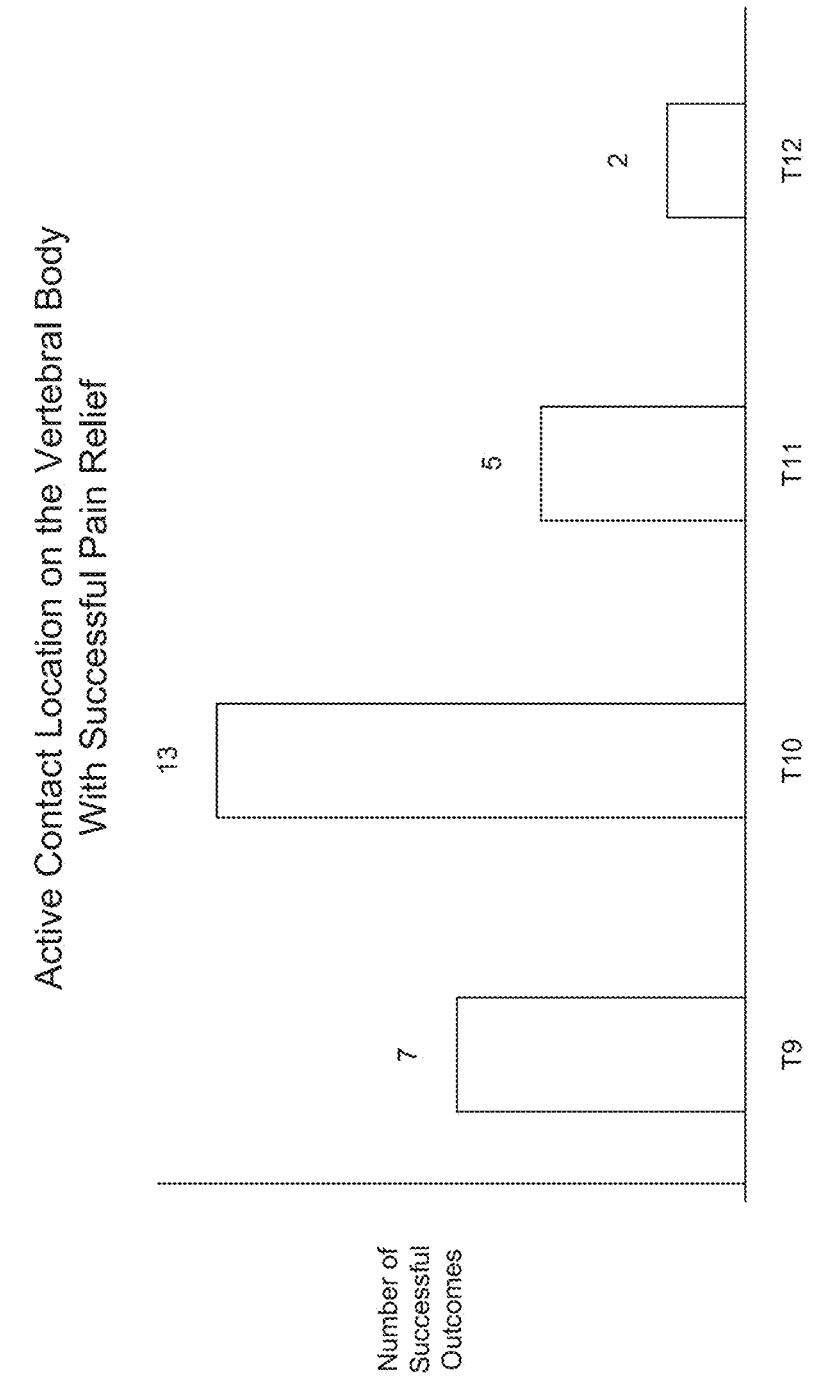
Active Contact Location on the Vertebral Body
With Successful Pain Relief
Number of Successful Outcomes
13
7
5
2
T9
T10
T11
T12
Vertebral Level

FIG. 13A

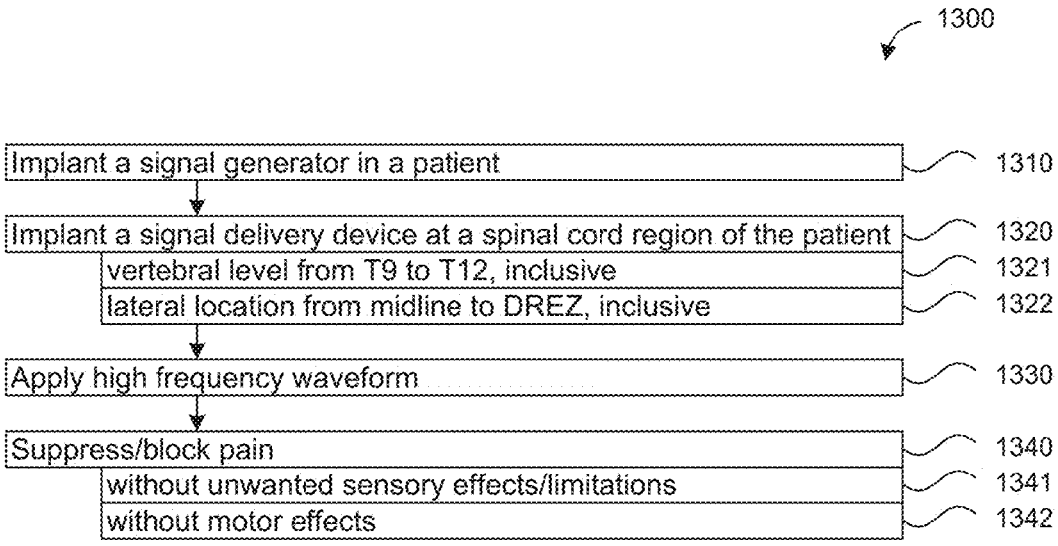

FIG. 13B

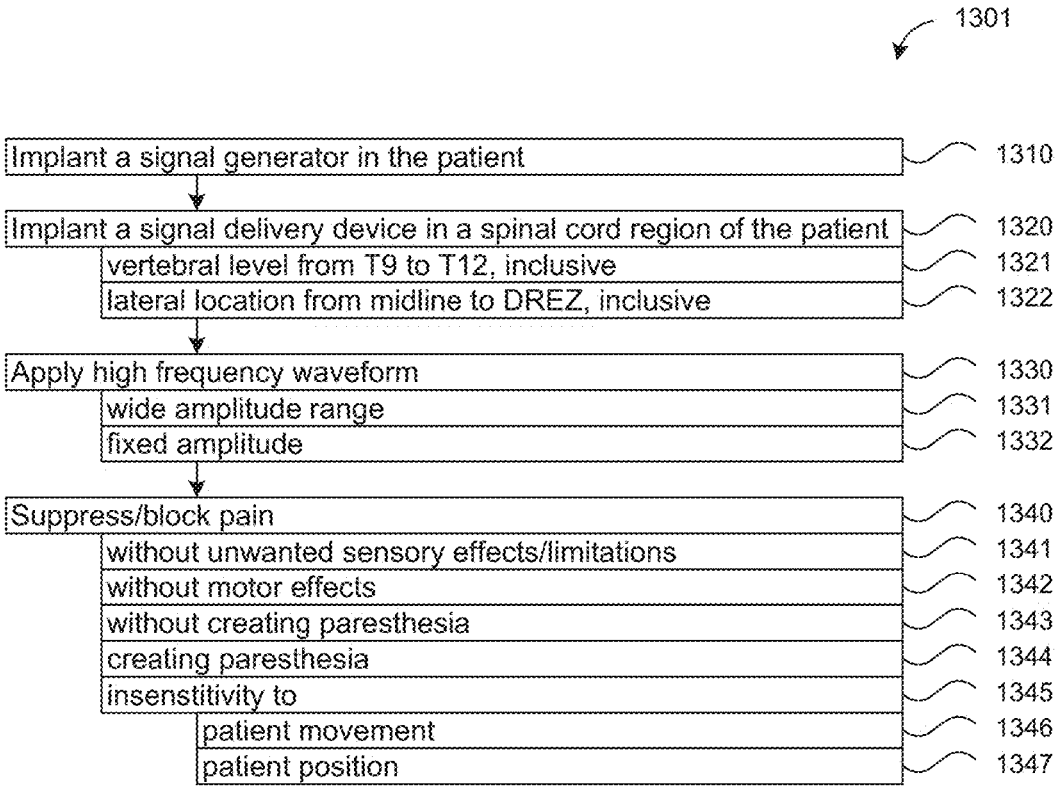

FIG. 13C

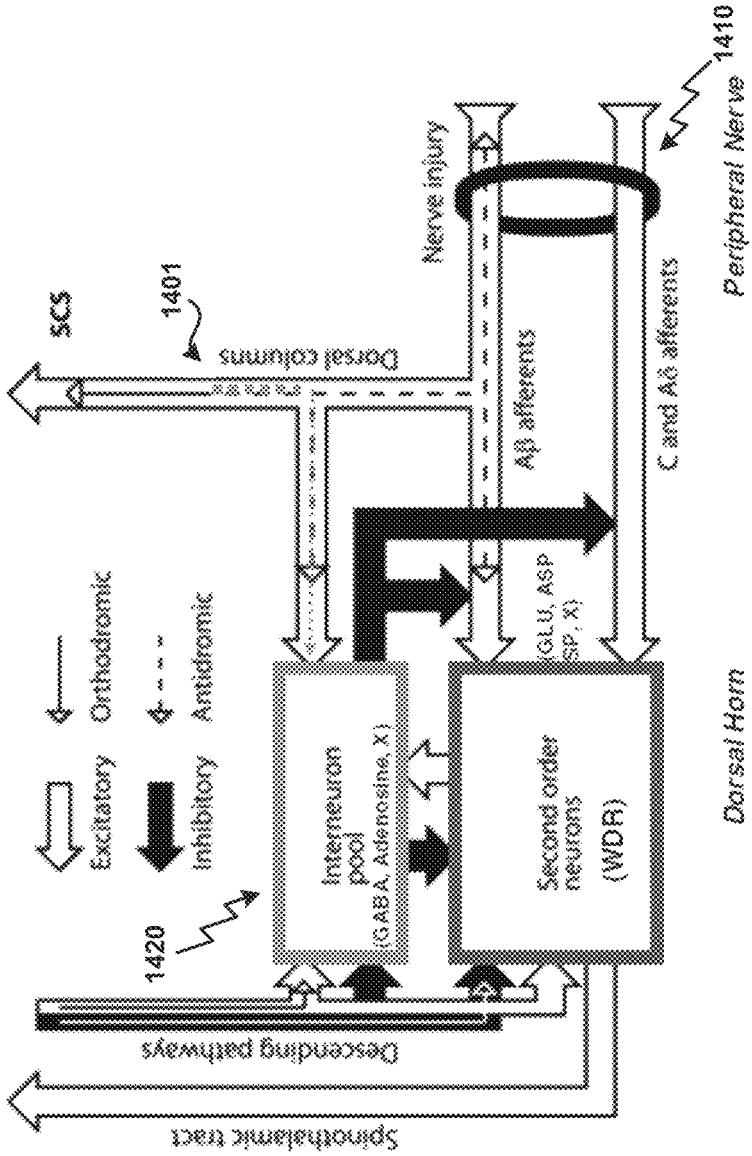
1410
Peripheral Nerve
Nerve injury
1401
SCS
Dorsal columns
Aβ afferents
C and Aδ afferents
Orthodromic
Antidromic
Excitatory
Inhibitory
(GLU, ASP SP, X)
Interneuron PDD (GABA, Adenosine, X)
Second order neurons (WDR)
Dorsal Horn
1420
Descending pathways
Spinothalamic tract

FIG. 14

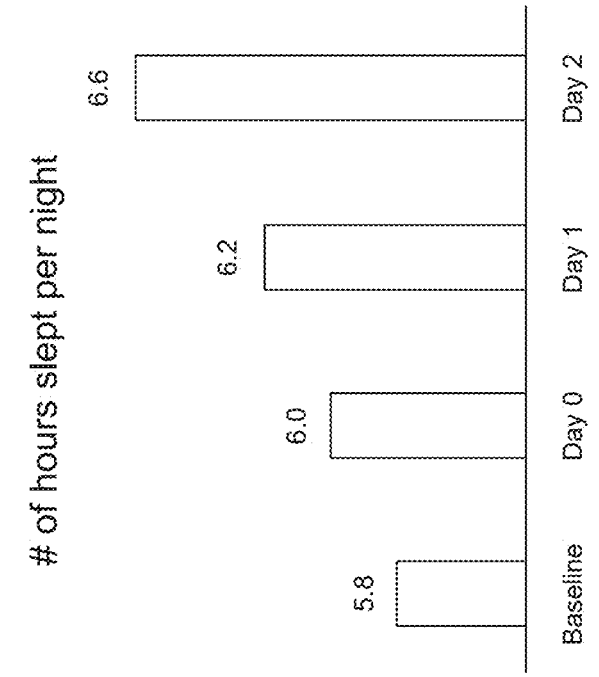

FIG. 15B

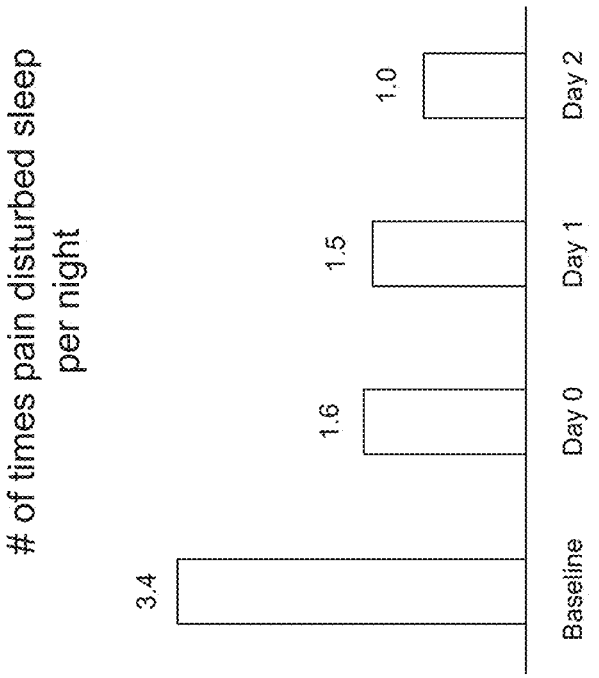

FIG. 15A

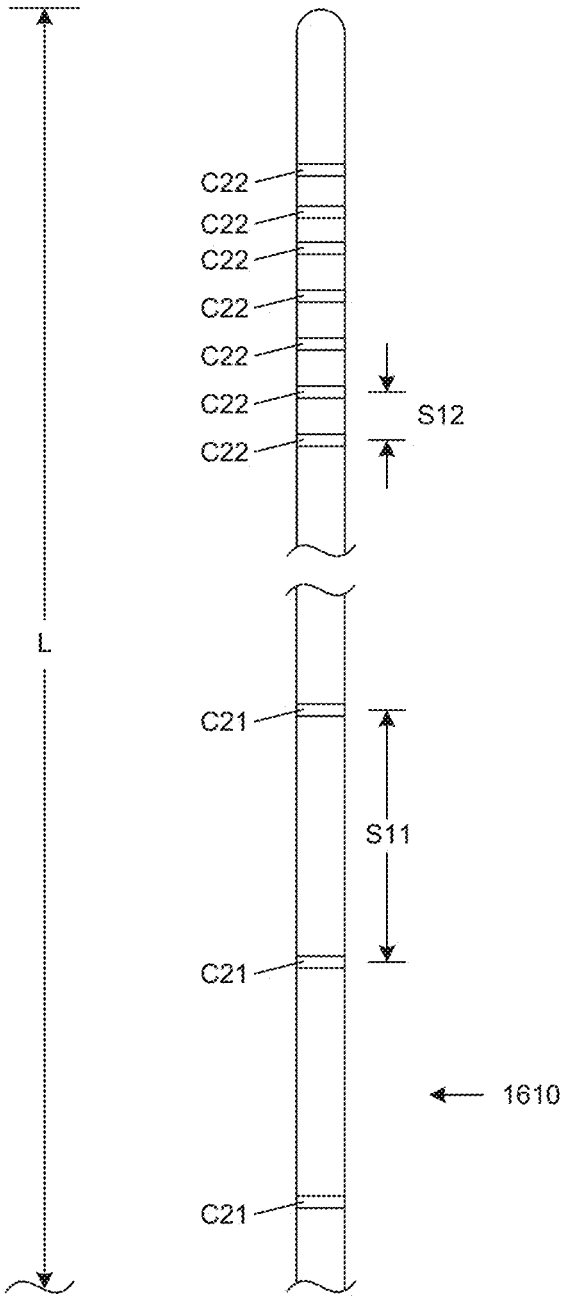

FIG. 16

LINKED AREA PARAMETER ADJUSTMENT FOR SPINAL CORD STIMULATION AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application No. 14/226,644, filed on Mar. 26, 2014, entitled "LINKED AREA PARAMETER ADJUSTMENT FOR SPINAL CORD STIMULATION AND ASSOCIATED SYSTEMS AND METHODS,"which is a continuation of U.S. patent application No. 13/914,494, now U.S. Pat. No. 8,712,535, filed Jun. 10, 2013, entitled "LINKED AREA PARAMETER ADJUSTMENT FOR SPINAL CORD STIMULATION AND ASSOCIATED SYSTEMS AND METHODS, "which is a continuation of U.S. patent application No. 12/510,930, now U.S. Pat. No. 8,498,710, filed on Jul. 28, 2009, entitled "LINKED AREA PARAMETER ADJUSTMENT FOR SPINAL CORD STIMULATION AND ASSOCIATED SYSTEMS AND METHODS,"which are incorporated herein by reference in their entireties.

TECHNICAL FIELD

The present technology is directed generally to spinal cord stimulation for managing pain, and associated systems and methods related to adjusting the amplitude, duty cycle and/or other parameters of the electrical waveform applied to the patient.

BACKGROUND

Neurological stimulators have been developed to treat pain, movement disorders, functional disorders, spasticity, cancer, cardiac disorders, and various other medical conditions. Implantable neurological stimulation systems generally have an implantable pulse generator and one or more leads that deliver electrical pulses to neurological tissue or muscle tissue. For example, several neurological stimulation systems for spinal cord stimulation (SCS) have cylindrical leads that include a lead body with a circular cross-sectional shape and one or more conductive rings or bands spaced apart from each other at the distal end of the lead body. The conductive rings operate as individual electrodes and, in many cases, the SCS leads are implanted percutaneously through a large needle inserted into the epidural space either with or without the assistance of a stylet.

Once implanted, the pulse generator applies electrical signals via the electrodes to modify the function of the patient's nervous system, such as altering the patient's responsiveness to sensory stimuli and/or altering the patient's motor-circuit output. In pain treatment, the electrical signals can generate sensations which mask or otherwise alter the patient's sensation of pain. For example, in many cases patients report a tingling or paresthesia that is perceived as more pleasant and/or less uncomfortable than the underlying pain sensation. Although this may be the case for many patients, many other patients may report less beneficial effects and/or results. Accordingly, there remains a need for improving the techniques and systems for addressing patient pain.

One particular challenge of implementing neurological stimulators to manage pain is that multiple parts or regions of the patient's body contribute to the pain perceived by the patient, and the individual contributions of the various regions vary over time. For example, patients generally experience different levels of back pain and/or lower extremity pain because of exertion, stress, movement (e.g., walking, bending, twisting, etc.), position (e.g., standing, sitting, etc.), and other factors. Patients accordingly change the parameters of the electrical waveform in some or all of the affected regions on an ongoing basis to effectively manage the pain.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a partially schematic illustration of an implantable spinal cord stimulation system positioned at the spine to deliver therapeutic signals in accordance with an embodiment of the present technology.

FIG. **1**B is a partially schematic illustration of a lead having electrode contacts that form elements of one or more therapy circuits associated with different areas of the patient that are modulated in accordance with methods of the present technology.

FIG. **2** is a flow diagram illustrating a process for managing pain using linked area parameter modulation.

FIG. **3**A is a flow diagram illustrating a routine for determining a therapy range of a waveform parameter associated with an area for use in the technology.

FIG. **3**B is a flow diagram illustrating another routine for determining the therapy range of a waveform parameter associated with an area for use in the technology.

FIGS. **4** and **5** are schematic illustrations of waveforms showing implementations of methods for linked area parameter modulation in accordance with the technology.

FIG. **6** is a flow diagram illustrating a process for managing pain using linked area modulation in accordance with another embodiment of the technology.

FIG. **7** is a flow diagram illustration another process for managing pain using linked area parameter modulation in accordance with a different embodiment of the technology.

FIG. **8** is a partially schematic, cross-sectional illustration of a patient's spine, illustrating representative locations for implanted lead bodies in accordance with embodiments of the disclosure.

FIG. **9** is a bar chart illustrating pain reduction levels for patients over a four day period of a clinical study, during which the patients received therapy in accordance with an embodiment of the disclosure, as compared with baseline levels and levels achieved with conventional spinal cord stimulation devices.

FIG. **10** is a bar chart comparing the number of times patients receiving therapy in accordance with an embodiment of the present disclosure during a clinical study initiated stimulation changes, as compared with similar data for patients receiving conventional spinal cord stimulation.

FIG. **11** is a bar chart illustrating activity performance improvements for patients receiving therapy in accordance with an embodiment of the disclosure, obtained during a clinical study.

FIG. **12** is a bar chart comparing activity performance levels for patients performing a variety of activities, obtained during a clinical study.

FIG. **13**A is a bar chart illustrating successful therapy outcomes as a function of stimulation location for patients receiving therapy in accordance with an embodiment of the disclosure, obtained during a clinical study.

FIGS. **13**B and **13**C are flow diagrams illustrating methods conducted in accordance with embodiments of the disclosure.

FIG. **14** is a schematic illustration identifying possible mechanisms of action for therapies in accordance with the present disclosure, as compared with an expected mechanism of action for conventional spinal cord stimulation.

FIGS. **15**A and **15**B are bar charts illustrating sleep improvement for patients receiving therapy in accordance with embodiments of the disclosure, obtained during a clinical study.

FIG. **16** is a partially schematic illustration of a lead body configured in accordance with an embodiment of the disclosure.

DETAILED DESCRIPTION

The invention herein described can be implemented in numerous ways, including as a process, a method, a routine, a device, an apparatus, a system, a composition of matter, an electrical waveform, a computer readable or operable medium such as a computer readable storage medium or a computer network wherein program instructions that are sent over optical or electronic communication links. In this specification, these implementations, or any other form that the invention may take, may be referred as present technology or invention.

The present technology is directed generally to spinal cord stimulation (SCS) systems and methods for managing pain in a patient using an electrical waveform (e.g., electrical signals). Specific details of certain embodiments of the disclosure are described below with reference to changing one or more parameters of the electrical waveform applied to different areas of the patient using a spinal cord stimulator. The disclosed systems and methods, however, may be used in the context of other stimulators and/or other patient conditions. Accordingly, some embodiments of the technology can have configurations, components, or procedures different than those described in this section, and other embodiments may eliminate particular components or procedures described below. A person of ordinary skill in the relevant art, therefore, will understand that the technology may have other embodiments with additional elements and/or other embodiments without several of the features shown and described below with reference to FIGS. **1A-16**

Overview

During the trial period and the course of the SCS therapy itself, the patients typically change the parameters of the waveforms applied to different areas along the spinal cord to optimize the therapy. For example, if the patient experiences leg and/or back pain that varies over time, patient position, and other factors, the patient inputs change commands via a patient programmer that causes the pulse generator to increase or decrease one or more parameters of the electrical waveform. In most SCS systems, the amplitude is the parameter that can be modulated by the patient. Current SCS systems and processes, however, use complex devices with multiple settings to change the amplitude across multiple areas. Conventional systems usually include a manual mode in which the patient experimentally determines a suitable combination of areas and the amplitudes to apply to those areas. Because patients typically perform this on a trial-and-error basis, it is often only marginally effective and time consuming. Conventional systems may also include a linked mode in which the amplitudes of the waveform applied to one or more areas are tied together so that the patient merely adjusts the amplitude. Conventional linked mode systems adjust the amplitudes equally across each area, but this can be ineffective because different areas typically have different maximum amplitude thresholds above which the patient experiences increased pain levels. As a result, existing linked mode systems are limited because the amplitude can only be adjusted to the extent that the stimulation does not exceed the level of the area having the lowest maximum amplitude threshold. Certain aspects of the present technology simplify this process and enhance the ability to quickly change the amplitude or other waveform parameter across a plurality of areas.

In some embodiments, the present technology includes an electrode device having a plurality of electrodes including at least a first electrode associated with a first area of the patient and a second electrode associated with a second area of the patient. The first area has a first therapy range for a waveform parameter, and the second area has a second therapy range for the waveform parameter. The electrode device may be configured to be implanted into a patient. The technology further includes a power supply, a waveform generator configured to generate the waveform and a computer readable medium operatively coupled to the waveform generator. In some embodiments, the technology further includes an implantable device configured to be coupled to the electrode device and the implantable device includes the power supply, the waveform generator configured to generate the waveform, and the computer-operable medium operatively coupled to the waveform generator.

The technology can include delivering an electrical waveform at a first level of the waveform parameter to a first electrode located at the first area and at a second level of the waveform parameter to a second electrode at the second area. The technology can further include changing the first level of the waveform parameter to an updated first level, setting the second level of the waveform parameter based on the scaling factor to an updated second level, and delivering the electrical waveform at the updated first level of the waveform parameter to the first electrode and at the updated second level of the waveform parameter to the second electrode. In the various embodiments, this can include changing the first level of the waveform parameter, automatically setting the second level of the waveform parameter based on a ratio or other relationship between the first therapy range and the second therapy range, and delivering the electrical waveform to the first electrode and at the first level to the second electrode at the second level.

In some embodiments the computer-operable medium is programmed to change the waveform parameter applied to the first electrode and automatically set the parameter for the waveform applied to the second electrode based on a relationship between the first therapy range and the second therapy range (e.g., a therapy range ratio or other scaling factor). For example, when a change command is received by the implantable device, the computer-operable medium can be programmed to (a) change the waveform parameter applied to the first electrode by a first increment and (b) set the waveform parameter applied to the second electrode by a second increment in direct proportion to a therapy range ratio of the first therapy range to the second therapy range. In a different example, when a set of change commands is received, such as by the implantable device, the computer-operable medium is programmed to (a) change the waveform parameter applied to the first electrode by a change increment for each change command received by the implantable device and (b) set the waveform parameter applied to the second electrode according to a best-fit approximation of the therapy range ratio. In this latter example the computer-operable medium can be programmed to set the waveform parameter applied to the second electrode either by changing the parameter applied to the second electrode by the same amount as the first electrode or by holding the parameter applied to the second electrode constant when the patient inputs a change command.

In some embodiments, the technology further includes determining and/or receiving a scaling factor of the waveform parameter based on a relationship between the first and the

second therapy ranges. The computer-operable medium can be programmed to receive a predetermined scaling factor of a waveform parameter based upon a relationship between a first therapy range for the waveform parameter at a first area of the patient and a second therapy range for the waveform parameter at a second area of the patient. Alternatively, the computer-operable medium can automatically calculate the scaling factor based upon the first and second therapy ranges.

In some embodiments, the technology further includes delivering an electrical waveform at a first level of the waveform parameter to the first electrode located at the first area of the patient and at a second level of the waveform parameter to the second electrode, and delivering an updated first level to the first electrode and delivering an updated second level of the waveform parameter to the second electrode. In one particular example, the computer program is programmed to change the level of the waveform parameter applied to the first electrode implanted at the first area of the patient to an updated first level, automatically set the second level of the waveform parameter based on a ratio or other relationship between the first therapy range and the second therapy range to an updated second level, and deliver the electrical waveform at the updated first level to the first electrode and at the updated second level to the second electrode.

In some embodiments, the computer-operable medium is programmed to prevent the waveform parameter applied to the first area from exceeding a first maximum and/or preventing the waveform parameter applied to the second area from exceeding a second maximum.

The waveform parameters for the foregoing technology can include the amplitude, impedance, voltage, pulse width, frequency, duty cycle and other parameters. For example, the waveform parameter can include the power delivered via the first electrode and/or the second electrode over a given period of time.

Representative Systems and Methods

In the following discussion, FIGS. **1A-1B** illustrate a representative implementation of a system **100** implanted in the spinal cord region of a patient **190**, and FIGS. **2-7** illustrate representative components of system, methods, routines, associated circuits, and/or waveforms for managing pain across multiple areas of a patient. FIG. **1A** schematically illustrates the treatment system **100** arranged relative to the general anatomy of the patient's spinal cord **191** to provide relief from chronic pain and/or other conditions. The system **100** can include a waveform generator **101**, which may be implanted subcutaneously within the patient **190** and coupled to an electrode device **109** (e.g., a signal delivery element). In a representative example, the electrode device **109** includes a lead or lead body **110** that carries features or elements for delivering therapy to the patient **190** after implantation. The waveform generator **101** can be connected directly to the lead body **110**, or it can be coupled to the lead body **110** via a communication link **102** (e.g., an extension). As used herein, the terms lead and lead body include any of a number of suitable substrates and/or support members that carry devices for providing therapy signals to the patient **190**. For example, the lead body **110** can include one or more electrodes or electrical contacts that direct electrical signals into the patient's tissue. In other embodiments, the electrode device **109** can include devices other than a lead body (e.g., a paddle) that also direct electrical signals and/or other types of signals to the patient **190**.

The waveform generator **101** can transmit electrical signals (i.e., waveforms) to the electrode device **109** that up-regulate (e.g., stimulate or excite) and/or down-regulate (e.g., block or suppress) target nerves. As used herein, and unless otherwise noted, the terms "stimulate" and "stimulation" refer generally to signals that have either type of effect on the target nerves, and the terms "electrical signals" and "electrical waveforms" are used interchangeably. The waveform generator **101** can include a machine-readable medium (e.g., computer-operable medium or computer-readable medium) programmed or otherwise containing instructions for generating and transmitting suitable therapy waveforms. The waveform generator **101** and/or other elements of the system **100** can include one or more processors **107**, memories **108** and/or input/output devices. Accordingly, the process of managing pain across multiple areas can be performed by computer-executable instructions contained on computer-operable media, e.g., the processor(s) **107** and/or memory(s) **108**. The waveform generator **101** can include multiple portions, elements, and/or subsystems (e.g., for directing signals in accordance with multiple signal delivery parameters) contained in a single housing, as shown in FIG. **1A**, or contained in multiple housings. In any of these embodiments, the waveform generator **101** and/or other implanted components of the system **100** can include elements for detecting and responding to patient movement, impedance changes or other variables.

In some embodiments, the waveform generator **101** receives power from an external power source **103**. The external power source **103** can transmit power to the implanted waveform generator **101** using electromagnetic induction (e.g., RF signals). For example, the external power source **103** can include an external coil **104** that communicates with a corresponding internal coil (not shown) within the implantable waveform generator **101**. The external power source **103** can be portable and rechargeable for ease of use.

In another embodiment, the waveform generator **101** can receive power from an internal power source in addition to or in lieu of the external power source **103**. For example, the implanted waveform generator **101** can include a battery that is either non-rechargeable or rechargeable to provide the power. When the internal power source includes a rechargeable battery, the external power source **103** can be used to recharge the battery. The external power source **103** can in turn be recharged from a suitable power source (e.g., conventional wall power).

In some cases, an external programmer **105** (e.g., a trial stimulator) can be coupled to the electrode device **109** during a trial procedure before implanting the waveform generator **101**. A practitioner (e.g., a physician and/or a company representative) can use the external programmer **105** to vary the stimulation parameters provided to the electrode device **109** in real time, and select optimal or particularly efficacious parameters. During the trial period, the practitioner can also vary the position of the electrode device **109**. After the position of the electrode device **109** and initial signal delivery parameters are established using the external programmer **105**, the trial period continues for a limited time period by providing the therapy to the patient **190** via signals generated by the external programmer **105**. In a representative application, the patient **190** receives the trial therapy for one week. If the trial therapy is effective or shows the promise of being effective, the practitioner then replaces the external programmer **105** with the implanted waveform generator **101**. The practitioner can optionally replace or reposition the electrode device **109** at the same time. The waveform parameters are initially based on the experience of the trial period, but these parameters can be further adjusted remotely via a wireless physician's programmer (e.g., a physician's remote) **111** and/or a wireless patient programmer **106** (e.g., a patient remote) at any time. Generally, the patient **190** has control over fewer parameters than the practitioner. For example, the capability

of the patient programmer **106** may be limited to starting/stopping the waveform generator **101** and adjusting the stimulation amplitude applied to one or more areas adjacent the electrode device **109**.

In any of the foregoing embodiments, the waveform parameters can be modulated during portions of the therapy regimen across one or more of the areas adjacent the electrode device **109**. For example, the frequency, amplitude, pulse width, duty cycle, and/or signal delivery location can be modulated in accordance with a preset program, patient and/or physician inputs, and/or in a random or pseudorandom manner. Such parameter variations can be used to address a number of potential clinical situations, including changes in the patient's perception of pain, changes in the preferred target neural population, and/or patient accommodation or habituation. In accordance with the present technology, one or more sets of areas adjacent to the signal delivery element **109** are linked together for the purpose of modulating one or more of the waveform parameters based on a scaling factor between the individual areas in each set. As explained in more detail below, the level of a waveform parameter applied to each area in a linked pair can be modulated based upon a scaling factor between the corresponding areas.

FIG. **1**B illustrates a representative lead **110** that can be connected to the waveform generator **101**. The lead **110** can have any suitable number of contacts C positioned along its length L for delivering electrical therapy to the patient. For purposes of illustration, the lead **110** can have 11 contacts C (identified individually as contacts C**1**, C**2** . . . C**11**). In operation, one or more of the contacts C is cathodic and another one or more of the contacts C is anodic. The contacts C can be individually addressable so that any contact C or combination of contacts C can operate as a cathode, and any contact C or combination of contacts C can operate as an anode. The contacts C can be electrically grouped in any of a wide variety of combinations, and individual contacts C can perform different functions (e.g., cathodic functions and/or anodic functions) at different times during the course of a therapy regimen. In any of these embodiments, each contact C may be coupled with a corresponding conductor **111** to the waveform generator **101**. The conductors **111** may have one or more connection points along their lengths (e.g., at a junction with the waveform generator **101**, and optionally at a junction with an extension). Accordingly, the circuit for a given pair of contacts C includes the contacts C, the patient tissue T between the contacts, the individual conductors **111**, connection points along the conductors **111**, and connection points between the conductors **111** and the waveform generator **101**.

FIG. **2** illustrates an overall process in accordance with a specific embodiment of the technology for managing pain in a patient using an electrical waveform. In this embodiment, the patient has a first area which has a first therapy range for a waveform parameter and a second area which has a second therapy range for the waveform parameter. The method **200** can include changing the level of the waveform parameter applied to a first electrode located at the first area of the patient (block **210**), and automatically setting the level of the waveform parameter applied to a second electrode located at the second area of the patient (block **220**). The level of the waveform parameter applied to the second electrode is automatically set by the computer-operable medium based on the magnitude of the change of the waveform parameter applied to the first electrode and a relationship between the first therapy range and the second therapy range (block **220**). The waveform parameter, for example, can be the amplitude, pulse width, duty cycle, frequency, power or other variable. The relationship between the first therapy range and the second therapy range can be a scaling factor that compensates for different sensation, therapy and pain thresholds between the first and second areas. The method **200** accordingly links the level of the waveform parameter applied to the second area of the patient to the level of the waveform parameter applied to the first area of the patient based on the relationship between the first and second therapy ranges for the waveform parameter.

The method **200** is not limited to linking the adjustment of the level of a single waveform parameter across different areas of the patient, but rather the method **200** can include linking changes in the levels of a set of parameters of the waveform applied to one area of the patient to the levels of the same set of parameters of the waveform applied to another area of the patient based on the scaling factor. The method **200** is also not limited to linking the adjustment for the level of just the first and second areas of the patient, but rather the method **200** can include linking the level of the waveform parameter to any number of areas of the patient's body in addition to, or in lieu of, linking the waveform parameter applied to the first and second electrodes located at the first and second areas of the patient. The use of "first" and "second" throughout is accordingly inclusive of additional like features, and thus unless otherwise expressly stated the use of "first" and "second" throughout does not exclude any additional like or similar features. In several embodiments, the method **200** includes changing the level of the waveform parameter applied to the first electrode and concurrently setting the level of the waveform parameter applied to the second electrode, but in other embodiments there can be a delay between changing the level of the waveform parameter applied to the first electrode and setting the level of the waveform parameter applied to the second electrode.

The different areas of the patient can be sites relative to the patient's spinal cord. For example, the first and second areas can be located adjacent to the patient's spinal cord such that the electrical waveform applied to the first area affects a first population of neurons while the waveform applied to the second area affects a second population of neurons. The first and second neuron populations can be completely distinct from each other, or in other situations there can be some overlap among the different neuron populations.

The different areas of the patient are generally associated with different areas of pain perceived by the patient. Referring to FIG. **1**B, for example, any of the electrodes C**1**-C**11** can be associated with individual areas of the patient to apply energy to different populations of neurons that control or are otherwise involved in the transmission of pain signals associated with different regions of the patient. The method **200** can further include locating more than one electrode at each individual area of the patient. For example, electrodes C**1**-C**4** can be located at a first area A_1 of the patient, electrodes C**5**-C**8** can be located adjacent to a second area A_2 of the patient, electrode C**9** can be located adjacent to a third area A_3 of the patient, and electrode C**10** can be located at a fourth area A_4 of the patient. In other embodiments, only a single one of the electrodes C**1**-C**11** can be located and/or activated at a single area of the patient. The configuration of areas A_1-A_4 shown in FIG. **1**B is merely one example, and a person skilled in the art of implementing SCS systems will understand that the number of areas and the number of electrodes per area varies and are not limited to those shown in FIG. **1**B.

The method **200** links the modulation of at least one waveform parameter across two areas of the patient. For example, two or more of the different areas of the patient A_1-A_4 can be linked together in one or more sets in which a scaling factor is applied to changes of a waveform parameter between the

different areas of a set. In one embodiment, areas A_1 and A_2 can be linked together to define a first area set in which a scaling factor S_1 is applied to the waveform parameter applied to each of the areas A_1 and A_2. Similarly, the third area A_3 and the fourth area A_4 can be linked together in a second area set in which a scaling factor S_2 is applied to the waveform parameter applied to the third and fourth areas A_3 and A_4 either in addition to, or in lieu of, applying the scaling factor S_1 to areas A_1 and A_2. FIG. **1**B further illustrates that the second area A_2 and the third area A_3 can be linked together in a third area set to which a scaling factor S_3 is applied to the waveform parameter applied to areas A_2 and A_3. Any number of different combinations of areas and scaling factors may be implemented for controlling the waveform parameters among the different areas of one or more area sets.

Several embodiments of the method **200** are particularly useful for controlling pain perceived in different regions of the back and/or lower extremities (e.g., legs, buttocks, foot). Referring to U.S. Patent Application No. 61/176,868, filed on May 8, 2009, now expired, which is incorporated herein by reference, the electrodes can be located adjacent to vertebral bodies T9-T12, and more specifically along vertebral bodies T10-T11, for treating back and lower extremity pain. In other embodiments, however, the electrodes can be located adjacent to other vertebral bodies for treating other types of pain or other conditions.

The scaling factor can be based on a relationship between the therapy ranges of the waveform parameter for the individual areas of the patient. The therapy range for a given area can be the range of the waveform parameter that provides the desired pain control without inducing discomfort (e.g., sharp pain, adverse muscle effects, or other unwanted effects). For example, the lower limit of a therapy range for a given area can be based on the level of the waveform parameter at a sensation threshold and/or a therapeutic threshold associated with the particular area. The upper limit of the therapy range for the particular area can be based on a level of the waveform parameter at a discomfort threshold. The "sensation threshold" can be the level or range of the waveform parameter at which the patient initially senses the electrical waveform applied to the specific area. The "therapeutic threshold" can be the level or range of the waveform parameter at which the patient experiences a therapeutic effect, such as relieving pain, associated with the corresponding area. The sensation and therapeutic thresholds can be the same or similar levels of the waveform parameter. The "discomfort threshold" can be the level or range of the waveform parameter that induces pain, unwanted muscle effects, or other undesirable effects associated with the corresponding area. The lower limit of the therapy waveform may be set slightly above the sensation threshold and/or the therapeutic threshold to provide a margin that ensures the patient receives the desired therapy. Conversely, the upper limit of the therapy range can be less than the discomfort threshold to provide a margin that ensures that the patient does not experience discomfort.

The method **200** can further include setting a maximum level for the waveform parameter at each of the areas of the patient. For example, the method **200** can further include setting a first maximum of the waveform parameter for the first area and setting a second maximum of the waveform parameter for the second area. The first and second maximums of the waveform parameter can be less than the first and second discomfort thresholds, respectively. The method **200** can further include preventing the first or second levels of the waveform parameter from exceeding the first or second maximums, respectively, so that the electrical waveform does not induce undesirable side effects in any of the linked areas.

The therapy ranges for the individual areas of the patient can be determined during the trial period and/or throughout the therapy after final implantation. FIG. **3**A is a flowchart illustrating an embodiment of a routine for determining the therapy range of the waveform parameter associated with an area of the patient. As described above, the electrodes are implanted in the patient and the electrical waveforms are generated by a waveform generator to determine whether the electrical signals provide a therapeutic effect for the specific patient. The embodiment of the routine **300** illustrated in FIG. **3**A includes determining a correlation between the electrodes and the areas of the patient (block **310**), delivering the electrical waveform to at least one electrode at a corresponding area of the patient (block **320**), and modulating a waveform parameter applied to the electrode (block **330**). The correlation between the electrodes and the areas of the patient can be determined by applying the electrical waveform to one or more electrodes either individually or in various combinations with each other and recording the corresponding areas where the patient perceives a sensation, a therapeutic effect, or discomfort. Based on the modulation of the waveform parameter, the method **300** further includes determining a level of the waveform parameter at which the patient perceives the application of the electrical waveform (block **340**) without discomfort and determining a level of the waveform parameter at which the patient perceives an undesirable effect (block **350**). The level of the waveform parameter at which the patient perceives the application of the electrical waveform (block **340**) without discomfort can correspond to the sensation threshold and/or the therapeutic threshold, and the level of the waveform parameter at which the patient perceives an undesirable effect (block **350**) can correspond to the discomfort threshold. As described above, the lower and upper limits of the therapy range can be based on these thresholds.

The therapy ranges can also be determined based on a patient usage history during the trial period and/or after final implantation of the pulse generator. FIG. **3**B illustrates a routine **312** for determining the therapy range in accordance with an embodiment of the technology. In this embodiment, the routine **312** includes applying an electrical waveform to electrodes at different areas of the patient (block **322**). The electrical waveform can be applied to one or more electrodes at the individual areas of the patient to determine the therapy ranges for the corresponding areas as explained above. The routine **312** further includes recording the waveform parameter levels applied to the different electrodes at the different areas of the patient (block **332**) over time. The usage history of the waveform parameter can be recorded in the onboard memory of the implantable device and then downloaded via a wireless communication link to an external programmer during recharging or at other times. The routine **312** further includes determining at least one of the sensation threshold or the therapeutic threshold from the usage data (block **342**) and determining the discomfort threshold from the usage data (block **352**). The routine **312** can optionally including determining the other of the sensation threshold or the therapeutic threshold from the usage data (block **362**) in addition to the threshold determined at block **362**. The sensation threshold, discomfort threshold and/or therapeutic threshold determined from the usage data can remain static throughout the therapy, or the routine can further include updating one or more of these thresholds on a continuous or periodic basis (block **372**).

The various thresholds at blocks **342**, **352** and **362** can be determined by having the patient provide an input when the patient perceives a sensation, a therapeutic effect or an unde-

sirable effect associated with the waveform. The patient inputs can be correlated with the levels of the waveform parameter to provide a series of data points for determining each of the sensation, therapeutic and/or discomfort thresholds. In a different embodiment, the thresholds can be based on an assessment of the patient's habits. For example, the lower limits of the therapy range can be determined by identifying the lower range of waveform parameter levels consistently used by the patient because such usage would indicate that the patient does not perceive the waveform or a therapeutic effect below such levels. The discomfort threshold may be assessed by ascertaining the levels of the waveform parameter at which the patient rapidly reduces the magnitude of the parameter and/or the upper range of waveform parameter levels used by the patient. A rapid reduction of the magnitude of the waveform parameter may be indicative of an acute increase in pain or other undesirable effects, whereas the upper range would indicate the patient perceives discomfort above such levels. The therapeutic threshold also may be determined by identifying the levels at which the waveform parameters are maintained for extended periods of time because this would indicate that the electrical waveform is providing the desired therapeutic effect for controlling or otherwise managing the patient's pain.

The actual linked modulation based on the relationships between the therapy ranges can be executed in a number of different ways. For example, one embodiment of the method **200** changes the level of the waveform parameter applied to the first area by a first increment and automatically changes the level of the waveform parameter applied to the second area by a second increment in direct proportion to the ratio of the first therapy range to the second therapy range. The ratio of the first therapy range to the second therapy range can be less than 1:1, equal to 1:1, or greater than 1:1 depending upon the sizes of the individual ranges. The ratio can have a positive value when the waveform parameter levels in different areas are positively correlated, and a negative value when the waveform parameter levels are negatively correlated. A negative correlation can exist, for example, when the patient experiences a stronger than desired stimulation in one area, and a weaker than desired stimulation in another area. In such instances, the scale factor can include the ratio described above, optionally modified by patient input.

When the amplitude is the waveform parameter being modulated, the ratio of the first therapy range for the first area of the patient to the second therapy range for the second area of the patient can be defined by the equation:

$$\text{Ratio} = \frac{A_{1P} - A_{1T}}{A_{2P} - A_{2T}}$$

In this equation, A_{1P} is the amplitude at which the patient experiences pain at the first area, A_{1T} is the amplitude at which the patient experiences a therapeutic effect at the first area, A_{1P} is the amplitude at which the patient experiences pain at the second area, and A_{2T} is the amplitude at which the patient experiences a therapeutic effect at the second area. In this embodiment, the change in the level of the waveform parameter applied to the second area is the product of the magnitude of the first increment that the waveform parameter was changed at the first area and the ratio of the first therapy range to the second therapy range.

FIG. **4** illustrates in a specific example of setting the waveform parameter applied to the second electrode in direct proportion to the therapy range ratio. The example shown in FIG. **4** is for purposes of illustration and is not limiting in any way. In this example, if the first area of the patient has a pain threshold (A_{1P}) of 6 mA and a therapy threshold (A_{1T}) of 3 mA, and if the second area of the patient has a pain threshold (A_{2P}) of 7 mA and a therapy threshold (A_{2T}) of 5 mA, then the first therapy range is 3 mA and the second therapy range is 2 mA. This results in a therapy range ratio of 3:2 based on the equation above. As a result, for every first increment that the waveform parameter is changed at the first area A_1, the second increment that the waveform parameter is changed at the second area A_2 is two-thirds of the first increment. If the therapy range ratio of the first therapy range to the second therapy range is 2:1, then the second increment is 50% of the first increment.

FIG. **5** illustrates another example of implementing an embodiment of the method **200** in which the levels of the waveform parameter are modulated to achieve a best-fit approximation of the relationship between the first and second therapy ranges. In this embodiment, each time the waveform parameter applied to the first electrode is changed by an incremental amount, the waveform parameter applied to the second electrode is set by either (a) changing the waveform parameter applied to the second area by the same incremental amount or (b) holding the waveform parameter applied to the second area constant. For example, when the therapy range ratio of the first therapy range to the second therapy range is 3:2 as described above, then the level of the waveform parameter applied to the second electrode is changed by two of the incremental amounts for every three incremental amounts that the level of the waveform parameter is changed at the first electrode. Stated differently, each time the patient pushes a button to increase or decrease the waveform parameter, the waveform parameter for the first electrode is changed by a full increment, but the waveform parameter is changed at the second area only every two out of three times that the patient pushes the button. FIG. **5** illustrates this point for the example of a therapy ratio of 3:2 at times t_1, t_2 and t_3. More specifically, when the patient pushes a button or otherwise inputs a change command using the patient programming at time t_1, the level of the parameter is increased by a first increment 1.0 at both the first area A_1 and the second area A_2. This provides the best fit for a 3:2 therapy ratio because the direct proportional increase at the second area A_2 would be approximately 0.67 such that applying an incremental change of 1.0 to area A_2 is closer to the therapy ratio than holding the value constant. At time t_2, the patient inputs another command to increase the waveform parameter by another full increment at area A_1 to 2.0, but the value of the waveform parameter applied to area A_2 is held constant. This is because after two increases of the incremental value applied to area A_1, the direct proportional value of the waveform parameter for area A_2 would be 1.33 such that holding the waveform parameter applied to the second area constant at 1.0 provides a better fit than increasing the waveform parameter applied to the second electrode to 2.0. At time t_3, the patient enters another input to change the waveform parameters such that the level of the waveform parameter associated with the first area A_1 is increased to 3.0 and the level of the waveform parameter associated with the second area A_2 is increased to 2.0. The foregoing examples using the ratio of 3:2 are merely for illustration, and it will be appreciated that the actual ratio of the first therapy range to the second therapy range can be any ratio depending upon the values for the first and second therapy ranges.

The method **200** can further include preventing a waveform parameter applied to the first area from exceeding a first maximum and preventing the waveform parameter applied to the second area from exceeding a second maximum. Because

each area of the patient may have a different maximum for the waveform parameter, the method **200** can include determining a first maximum for the waveform parameter associated with the first area and determining a second maximum for the waveform parameter associated with the second area above which application of the waveform causes discomfort at either or both of the areas. By preventing the waveform parameter from exceeding one or both of the first and/or second maximums, the patient will not exceed the pain threshold of one area while trying to increase the amplitude applied to another area.

FIG. **6** is a flowchart illustrating a method **600** in accordance with another embodiment of the technology. In this embodiment, the method **600** includes delivering an electrical waveform at a first level of the waveform parameter to a first electrode at the first area and at a second level of the waveform parameter to a second electrode at the second area (block **610**). The method **600** further includes changing the first level of the parameter (block **620**) and setting the second level of the parameter based on a ratio of the first therapy range to the second therapy range (block **630**). The electrical waveform is then delivered at the first level of the parameter to the first electrode and at the second level of the parameter to the second electrode (block **640**).

FIG. **7** illustrates a method **700** in accordance with yet another embodiment of the technology. In this embodiment, the method **700** includes selecting at least two areas for linked modulation of the waveform parameter including a first area having a first therapy range for the waveform parameter and a second area having a second therapy range for the waveform parameter (block **710**). The method **700** further includes determining a scaling factor of the waveform parameter based on a relationship between the first and second therapy ranges (block **720**). The method **700** continues by delivering an electrical waveform at a first level of the waveform parameter to a first electrode located at the first area and at a second level of the waveform parameter to a second electrode located at the second area (block **730**). The method **700** further includes changing the first level of the waveform parameter to an updated first level (block **740**) and setting the second level of the waveform parameter to an updated second level based on the scaling factor and the magnitude of the change of the first level of the waveform parameter (block **750**). The electrical waveform is then delivered at the updated first level of the waveform parameter to the first electrode and at the updated second level of the waveform parameter to the second electrode (block **760**).

In any of the foregoing embodiments, the computer-operable medium of the system **100** can be programmed to execute any or all of the embodiments of the methods described above. Additionally, the system **100** can further comprise a memory containing a history of patient usage patterns of the waveform applied to the first and second electrodes, and the computer-operable medium can be programmed to determining whether the first area of the patient is linked to the second area of the patient. In still additional embodiments, the computer-operable medium can be programmed to determine whether the first area of the patient is not linked to the second area of the patient, and in such circumstances to change the first waveform parameter applied to the first electrode and set the second waveform parameter applied to the second electrode independently of each other.

Any of the foregoing methods and systems can include further embodiments for adapting the linked modulation of the waveform parameter to the position of the patient. For example, the system **100** can further comprise a memory including a first ratio of the first therapy range to the second therapy range associated with a first patient position and a second ratio of the first therapy range to the second therapy range associated with a second patient position. The system can further comprise a position detector, and the computer-operable medium can be programmed to change the waveform parameter applied to the first electrode and set the waveform parameter applied to the second electrode based on (a) the first ratio when the position detector indicates that the patient is in the first patient position or (b) the second ratio when the position detector indicates that the patient is in the second patient position. The position detector can comprise an accelerometer, or the position detector can comprise an impedance detector.

Several embodiments of the systems, methods and routines of the technology described above can simplify and enhance the ability to change a waveform parameter across several areas of the patient. For example, the patient can merely increase or decrease the intensity of the waveform parameter and the systems and methods automatically adjust the waveform parameter across the different areas without being limited by the area with the lowest pain threshold or the highest therapeutic threshold. As explained above, existing linked mode systems that do not provide scaling between the various areas are limited to increasing the intensity of the waveform parameter so that it does not exceed the pain threshold level of the area having the lowest pain threshold. Many embodiments of the present technology avoid or mitigate such a limitation because the scaling factor allows the intensity of the parameter to be increased differently across the areas depending on the different pain thresholds. This enables some areas to receive more intense stimulation that would otherwise cause pain in areas with lower pain thresholds. Several embodiments of the technology also maintain the relative levels of the waveform parameter over a long period of time to provide more consistent results. Existing linked mode systems change the intensity of the waveform parameter at different areas by equal increments for each change command and merely prevent the waveform parameter from exceeding an upper limit at each area, but these systems then allow the waveform parameter to be decreased from their maximums by equal increments when the patient inputs the change commands. Several embodiments of the technology avoid or mitigate this problem because the scaling factor enables the waveform parameter to be changed by different amounts at different areas. Therefore, several embodiments of the technology simplify the ongoing modulation of waveform parameters and enhance the efficacy of managing pain.

Representive Therapy Parameters

Nevro corporation, the assignee of the present application, has conducted a multi-site clinical study during which multiple patients were first treated with conventional spinal cord stimulation (SCS) techniques, and then with newly developed techniques that are disclosed further below. Multiple embodiments of the newly developed techniques and/or therapies are referred to collectively herein as presently disclosed techniques and/or presently disclosed therapies.

Prior to the clinical study, selected patients were identified as suffering from primary chronic low back pain (e.g., neuropathic pain, and/or nociceptive pain, and/or other types of pain, depending upon the patient), either alone or in combination with pain affecting other areas, typically the patient's leg. In all cases, the low back pain was dominant. During the study, the patients were outfitted with two leads, each implanted in the spinal region in a manner generally similar to that shown in FIG. **1**A. One lead was implanted on one side of the spinal cord midline, and the other lead was implanted on

the other side of the spinal cord midline. FIG. **8** is a cross-sectional illustration of the spinal cord **191** and an adjacent vertebra **895** (based generally on information from Crossman and Neary, "Neuroanatomy," 1995 (published by Churchill Livingstone)), along with the locations at which leads **810** were implanted in a representative patient. The spinal cord **191** is situated between a ventrally located ventral body **896** and the dorsally located transverse process **898** and spinous process **897**. Arrows V and D identify the ventral and dorsal directions, respectively. The spinal cord **191** itself is located within the dura mater 899, which also surrounds portions of the nerves exiting the spinal cord 191, including the dorsal roots **893** and dorsal root ganglia **894**. The leads **810** were positioned just off the spinal cord midline **889** (e.g., about 1 mm. offset) in opposing lateral directions so that the two leads **810** were spaced apart from each other by about 2 mm.

Patients with the leads **810** located as shown in FIG. **8** initially had the leads positioned at vertebral levels T7-T8. This location is typical for standard SCS treatment of low back pain because it has generally been the case that at lower (inferior) vertebral levels, standard SCS treatment produces undesirable side effects, and/or is less efficacious. Such side effects include unwanted muscle activation and/or pain. Once the leads **810** were implanted, the patients received standard SCS treatment for a period of five days. This treatment included stimulation at a frequency of less than 1500 Hz (e.g., 60-80 Hz), a pulse width of 100-200 μsec, and a duty cycle of 100%. The amplitude of the signal (e.g., the current amplitude) was varied from about 3 mA to about 10 mA. The amplitude was initially established during the implant procedure. The amplitude was then changed by the patient on an as-desired basis during the course of the study, as is typical for standard SCS therapies.

After the patient completed the standard SCS portion of the study, the patient then received stimulation in accordance with the presently disclosed techniques. One aspect of these techniques included moving the leads **810** inferiorly, so as to be located at vertebral levels T9, T10, T11, and/or T12. After the leads **810** were repositioned, the patient received therapeutic stimulation at a frequency of from about 3kHz to about 10 kHz. In particular cases, the therapy was applied at 8 kHz, 9 kHz or 10KHz. These frequencies are significantly higher than the frequencies associated with standard SCS, and accordingly, stimulation at these and other representative frequencies (e.g., from about 1.5 kHz to about 100 kHz) is occasionally referred to herein as high frequency stimulation. The stimulation was applied generally at a duty cycle of from about 50% to about 100%, with the stimulation signal on for a period of from about 1 msec. to about 2 seconds, and off for a period of from about 1msec. to about 1.5 seconds. The width of the applied pulses was about 30-35 μsec., and the amplitude generally varied from about 1 mA to about 4 mA (nominally about 2.5 mA). Stimulation in accordance with the foregoing parameters was typically applied to the patients for a period of about four days during the clinical study.

FIGS. **9-13**A graphically illustrate summaries of the clinical results obtained by testing patients in accordance with the foregoing parameters. FIG. **9** is a bar chart illustrating the patients' Visual Analog Scale (VAS) pain score for a variety of conditions. The scores indicated in FIG. **9** are for overall pain. As noted above, these patients suffered primarily from low back pain and accordingly, the pain scores for low back pain alone were approximately the same as those shown in FIG. **9**. Each of the bars represents an average of the values reported by the multiple patients involved in this portion of the study. Bars **901** and **902** illustrate a baseline pain level of 8.7 for the patients without the benefit of medication, and a baseline level of 6.8 with medication, respectively. After receiving a lead implant on day zero of the study, and initiating high frequency stimulation in accordance with the foregoing parameters, patients reported an average pain score of about 4.0, as represented by bar **903**. Over the course of the next three days, (represented by bars **904-913**) the patients recorded pain levels in a diary every morning, midday and evening, as indicated by the correspondingly labeled bars in FIG. **9**. In addition, pain levels were recorded daily by the local center research coordinator on case report forms (CRFs) as indicated by the correspondingly labeled bars in FIG. **9**. During this time period, the patients' average pain score gradually decreased to a reported minimum level of about 2.2 (represented by bars **912** and **913**).

For purposes of comparison, bar **914** illustrates the pain score for the same patients receiving standard SCS therapy earlier in the study. Bar **914** indicates that the average pain value for standard SCS therapy was 3.8. Unlike the results of the presently disclosed therapy, standard SCS therapy tended to produce relatively flat patient pain results over the course of several days. Comparing bars **913** and **914**, the clinical results indicate that the presently disclosed therapy reduced pain by 42% when compared with standard SCS therapy.

Other pain indices indicated generally consistent results. On the Oswestry Disability Index, average scores dropped from a baseline value of 54 to a value of 33, which is equivalent to a change from "severe disability" to "moderate disability".

Patients' global improvement scores ranked 1.9 on a scale of 1 ("very much improved") to 7 ("very much worse").

In addition to obtaining greater pain relief with the presently disclosed therapy than with standard SCS therapy, patients experienced other benefits as well, described further below with reference to FIGS. **10-12**. FIG. **10** is a bar chart illustrating the number of times per day that the patients initiated stimulation changes. Results are illustrated for standard SCS therapy (bar **1001**) and the presently disclosed therapy (bar **1002**). The patient-initiated stimulation changes were generally changes in the amplitude of the applied signal, and were initiated by the patient via an external stimulator or remote, such as was described above with reference to FIG. **1**A. Patients receiving standard SCS therapy initiated changes to the stimulation parameters an average of 44 times per day. The initiated changes were typically triggered when the patient changed position, activity level, and/or activity type, and then experienced a reduction in pain relief and/or an unpleasant, uncomfortable, painful, unwanted or unexpected sensation from the therapeutic signal. Patients receiving the presently disclosed therapy did not change the stimulation parameters at all, except at the practitioners' request. In particular, the patients did not change signal amplitude to avoid painful stimulation. Accordingly, FIG. **10** indicates that the presently disclosed therapy is significantly less sensitive to lead movement, patient position, activity level and activity type than is standard SCS therapy.

FIG. **11** is a bar graph illustrating activity scores for patients receiving the presently disclosed therapy. The activity score is a quality of life score indicating generally the patients' level of satisfaction with the amount of activity that they are able to undertake. As indicated in FIG. **11**, bar **1101** identifies patients having a score of 1.9 (e.g., poor to fair) before beginning therapy. The score improved over time (bars **1102-1104**) so that at the end of the second day of therapy, patients reported a score of nearly **3** (corresponding to a score of "good"). It is expected that in longer studies, the patients' score may well improve beyond the results shown in FIG. **11**. Even the results shown in FIG. **11**, however, indicate a 53%

improvement (compared to baseline) in the activity score for patients receiving the presently disclosed therapy over a three day period. Anecdotally, patients also indicated that they were more active when receiving the presently disclosed therapy than they were when receiving standard SCS therapy. Based on anecdotal reports, it is expected that patients receiving standard SCS therapy would experience only a 10-15% improvement in activity score over the same period of time.

FIG. **12** is a bar chart illustrating changes in activity score for patients receiving the presently disclosed therapy and performing six activities: standing, walking, climbing, sitting, riding in a car, and eating. For each of these activities, groups of bars (with individual groups identified by reference numbers **1201**, **1202**,**1203** . . . **1206**) indicate that the patients' activity score generally improved over the course of time. These results further indicate that the improvement in activity was broad-based and not limited to a particular activity. Still further, these results indicate a significant level of improvement in each activity, ranging from 30% for eating to 80%-90% for standing, walking and climbing stairs. Anecdotally, it is expected that patients receiving standard SCS treatment would experience only about 10%-20% improvement in patient activity. Also anecdotally, the improvement in activity level was directly observed in at least some patients who were hunched over when receiving standard SCS treatment, and were unable to stand up straight. By contrast, these patients were able to stand up straight and engage in other normal activities when receiving the presently disclosed therapy.

Based on additional patient feedback, every one of the tested patients who received the presently disclosed therapy at the target location (e.g., who received the presently disclosed therapy without the lead migrating significantly from its intended location) preferred the presently disclosed therapy to standard SCS therapy. In addition, irrespective of the level of pain relief the patients received, 88% of the patients preferred the presently disclosed therapy to standard SCS therapy because it reduced their pain without creating paresthesia. This indicates that while patients may prefer paresthesia to pain, a significant majority prefer no sensation to both pain and paresthesia. This result, obtained via the presently disclosed therapy, is not available with standard SCS therapies that are commonly understood to rely on paresthesia (i.e., masking) to produce pain relief.

Still further, anecdotal data indicate that patients receiving the presently disclosed therapy experienced less muscle capture than they experienced with standard SCS. In particular, patients reported a lack of spasms, cramps, and muscle pain, some or all of which they experienced when receiving standard SCS. Patients also reported no interference with volitional muscle action, and instead indicated that they were able to perform motor tasks unimpeded by the presently disclosed therapy. Still further, patients reported no interference with other sensations, including sense of touch (e.g., detecting vibration), temperature and proprioception. In most cases, patients reported no interference with nociceptive pain sensation. However, in some cases, patients reported an absence of incision pain (associated with the incision used to implant the stimulation lead) or an absence of chronic peripheral pain (associated with arthritis). Accordingly, in particular embodiments, aspects of the currently disclosed techniques may be used to address nociceptive pain, including acute peripheral pain, and/or chronic peripheral pain, as will be discussed in greater detail later.

FIG. **13**A is a bar chart indicating the number of successful therapeutic outcomes as a function of the location (indicated by vertebral level) of the active contacts on the leads that provided the presently disclosed therapy. In some cases, patients obtained successful outcomes when stimulation was provided at more than one vertebral location. As indicated in FIG. **13**A, successful outcomes were obtained over a large axial range (as measured in a superior-inferior direction along the spine) from vertebral bodies T9 to T12. This is a surprising result in that it indicates that while there may be a preferred target location (e.g., around T10), the lead can be positioned at a wide variety of locations while still producing successful results. In particular, neighboring vertebral bodies are spaced apart from each other by approximately 32 millimeters (depending on specific patient anatomy), and so successful results were obtained over a broad range of four vertebral bodies (about 128 mm.) and a narrower range of one to two vertebral bodies (about 32-64 mm.). By contrast, standard SCS data generally indicate that the therapy may change from effective to ineffective with a shift of as little as 1mm. in lead location. As will be discussed in greater detail later, the flexibility and versatility associated with the presently disclosed therapy can produce significant benefits for both the patient and the practitioner.

FIGS. **13**B and **13**C are flow diagrams illustrating methods for treating patients in accordance with particular embodiments of the present disclosure. FIG. **13**B illustrates a method **1300** that includes implanting a signal generator in a patient (block **1310**). The signal generator can be implanted at the patient's lower back or other suitable location. The method **1300** further includes implanting a signal delivery device (e.g., a lead, paddle or other suitable device) at the patient's spinal cord region (block **1320**). This portion of the method can in turn include implanting the device at a vertebral level ranging from T9 to T12, inclusive (block **1321**), and at a lateral location ranging from the spinal cord midline to the DREZ, inclusive (block **1322**). At block **1330**, the method includes applying a high frequency waveform, via the signal generator and the signal delivery device. In particular examples, the frequency of the signal (or at least a portion of the signal) can be from about 1.5 kHz to about 100 kHz, or from about 1.5 kHz to about 50 kHz., or from about 3 kHz to about 20 kHz, or from about 5 kHz to about 15 kHz, or from about 3 kHz to about 10 kHz. The method **1300** further includes blocking, suppressing, inhibiting or otherwise reducing the patient's pain, e.g., low back pain (block **1340**). This portion of the method can in turn include reducing pain without unwanted sensory effects and/or limitations (block **1341**), and/or without motor effects (block **1342**). For example, block **1341** can include reducing or eliminating pain without reducing patient perception of other sensations, and/or without triggering additional pain. Block **1342** can include reducing or eliminating pain without triggering muscle action and/or without interfering with motor signal transmission.

FIG. **13**C illustrates a method **1301** that includes features in addition to those described above with reference to FIG. **13**B. For example, the process of applying a high frequency waveform (block **1330**) can include doing so over a wide amplitude range (e.g., less than 1 mA to about 8 mA) without creating unwanted side effects, such as undesirable sensations and/or motor interference (block **1331**). In another embodiment, the process of applying a high frequency waveform can include applying the waveform at a fixed amplitude (block **1332**). As described further later, each of these aspects can provide patient and/or practitioner benefits.

The process of blocking, suppressing or otherwise reducing patient pain (block **1340**) can include doing so without creating paresthesia (block **1343**), or in association with a deliberately generated paresthesia (block **1344**). As noted above, clinical results indicate that most patients prefer the absence of paresthesia to the presence of paresthesia, e.g.,

because the sensation of paresthesia may change to an uncomfortable or painful sensation when the patient changes position and/or adjusts the signal amplitude. However, in some cases, patients may prefer the sensation of paresthesia, and so can have the option of receiving it. In other cases, paresthesia may be used by the practitioner for site selection (e.g., to determine the location at which active electrodes are positioned). In addition to the above, reducing patient pain can include doing so with relative insensitivity to patient attributes that standard SCS is normally highly sensitive to (block **1345**). These attributes can include patient movement (block **1346**) and/or patient position (block **1347**).

FIG. **14** is a schematic diagram (based on Linderoth and Foreman, "Mechanisms of Spinal Cord Stimulation in Painful Syndromes: Role of Animal Models," Pain Medicine, Vol. 51, 2006) illustrating an expected mechanism of action for standard SCS treatment, along with potential mechanisms of action for therapy provided in accordance with embodiments of the present technology. When a peripheral nerve is injured, it is believed that the Aδ and C nociceptors provide an increased level of excitatory transmitters to second order neurons at the dorsal horn of the spinal cord. Standard SCS therapy, represented by arrow **1401**, is expected to have two effects. One effect is an orthodromic effect transmitted along the dorsal column to the patient's brain and perceived as paresthesia. The other is an antidromic effect that excites the interneuron pool, which in turn inhibits inputs to the second order neurons.

One potential mechanism of action for the presently disclosed therapy is represented by arrow **1410**, and includes producing an incomplete conduction block (e.g., an incomplete block of afferent and/or efferent signal transmission) at the dorsal root level. This block may occur at the dorsal column, dorsal horn, and/or dorsal root entry zone, in addition to or in lieu of the dorsal root. In any of these cases, the conduction block is selective to and/or preferentially affects the smaller Aδ and/or C fibers and is expected to produce a decrease in excitatory inputs to the second order neurons, thus producing a decrease in pain signals supplied along the spinal thalamic tract.

Another potential mechanism of action (represented by arrow **1420** in FIG. **14**) includes more profoundly activating the interneuron pool and thus increasing the inhibition of inputs into the second order neurons. This can, in effect, potentially desensitize the second order neurons and convert them closer to a normal state before the effects of the chronic pain associated signals have an effect on the patient.

The foregoing mechanisms of action are identified here as possible mechanisms of action that may account for the foregoing clinical results. In particular, these mechanisms of action may explain the surprising result that pain signals transmitted by the small, slow Aδ and C fibers may be inhibited without affecting signal transmission along the larger, faster Aβ fibers. This is contrary to the typical results obtained via standard SCS treatments, during which stimulation signals generally affect Aβ fibers at low amplitudes, and do not affect Aδ and C fibers until the signal amplitude is so high as to create pain or other unwanted effects transmitted by the Aβ fibers. However, aspects of the present disclosure need not be directly tied to such mechanisms. In addition, aspects of both the two foregoing proposed mechanisms may in combination account for the observed results in some embodiments, and in other embodiments, other mechanisms may account for the observed results, either alone or in combination with either one of the two foregoing mechanisms. One such mechanism includes an increased ability of high frequency stimulation (compared to standard SCS stimulation) to penetrate through the cerebral spinal fluid (CSF) around the spinal cord.

Another such mechanism is the expected reduction in impedance presented by the patient's tissue to high frequencies, as compared to standard SCS frequencies. Although the higher frequencies associated with the presently disclosed techniques may initially appear to require more power than conventional SCS techniques, the signal amplitude may be reduced when compared to SCS values (due to improved signal penetration) and/or the duty cycle may be reduced (due to persistence effects described later). Accordingly, the presently disclosed techniques can result in a net power savings when compared with standard SCS techniques.

Expected Benefits Associated with Certain Embodiments

Certain of the foregoing embodiments can produce one or more of a variety of advantages, for the patient and/or the practitioner, when compared with standard SCS therapies. Some of these benefits were described above. For example, as described above, the patient can experience a significant pain reduction that is largely independent of the patient's movement and position. In particular, the patient can assume a variety of positions and/or undertake a variety of movements associated with activities of daily living and/or other activities, without the need to adjust the parameters in accordance with which the therapy is applied to the patient (e.g., the stimulation amplitude). This result can greatly simplify the patient's life and reduce the effort required by the patient to experience pain relief while engaging in a variety of activities.

The foregoing result can have particular advantages for patients who otherwise experience significant sleep disturbances. Such patients may establish a stimulation parameter at a particular level when lying prone. When the patient rolls over while sleeping, the patient may experience a significant enough change in the pain reduction provided by standard SCS treatments to cause the patient to wake. In many cases, the patient may additionally experience pain generated by the stimulation signal itself, on top of the pain the stimulation signal is intended to reduce. With the presently disclosed techniques, by contrast, this undesirable effect can be avoided. FIGS. **15**A and **15**B illustrate the average effect on sleep for clinical patients receiving the presently disclosed therapy. FIG. **15**A illustrates the reduction in patient disturbances, and

FIG. **15**B illustrates the increase in number of hours slept. In other embodiments, the patient may be able to perform other tasks with reduced pain. For example, patients may drive without having to adjust the therapy level provided by the implanted device. Accordingly, the presently disclosed therapy may be more readily used by patients in such situations and/or other situations that improve the patients' quality of life.

Another benefit observed during the clinical studies described above is that when the patient does experience a change in the therapy level, it is a gradual change. This is unlike typical changes associated with conventional SCS therapies. With conventional SCS therapies, if a patient changes position or changes an amplitude setting, the patient can experience a sudden onset of pain, often described by patients as unbearable. By contrast, patients in the clinical study described above, when treated with the presently disclosed therapy, reported a gradual onset of pain when signal amplitude was increased beyond a threshold level, with the pain described as gradually becoming uncomfortable. One patient described a sensation akin to a cramp coming on, but never fully developing. This significant difference in patient response to changes in signal delivery parameters can allow

the patient to more freely change stimulation parameters and/or posture when desired, without fear of creating an immediately painful effect.

Another observation from the clinical studies described above is that the amplitude "window" between the onset of effective therapy and the onset of pain or discomfort is relatively broad, and in particular, broader than it is for standard SCS treatment. For example, during standard SCS treatment, the patient typically experiences a pain reduction at a particular amplitude, and begins experiencing pain from the therapeutic signal (which may have a sudden onset, as described above) at about 1.6 times that amplitude. This corresponds to a dynamic range of about 1.6. In addition, patients receiving standard SCS stimulation typically wish to receive the stimulation at close to the pain onset level because the therapy is often most effective at that level. Accordingly, patient preferences may further reduce the effective dynamic range. By contrast, therapy in accordance with the presently disclosed embodiments resulted in patients obtaining pain relief at 1 mA or less, and not encountering pain or muscle capture until the applied signal had an amplitude of 4 mA, and in some cases up to about 8 mA, corresponding to a much larger dynamic range. Even at the forgoing amplitude levels, the pain experienced by the patients was significantly less that that associated with standard SCS pain onset. An expected advantage of this result is that the patient and practitioner can have significantly wider latitude in selecting an appropriate therapy amplitude with the presently disclosed methodology than with standard SCS methodologies. For example, the practitioner can increase the signal amplitude in an effort to affect more (e.g., deeper) fibers at the spinal cord, without triggering unwanted side effects. The existence of a wider amplitude window may also contribute to the relative insensitivity of the presently disclosed therapy to changes in patient posture and/or activity. For example, if the relative position between the implanted lead and the target neural population changes as the patient moves, the effective strength of the signal when it reaches the target neural population may also change. When the target neural population is insensitive to a wider range of signal strengths, this effect can in turn allow greater patient range of motion without triggering undesirable side effects.

Although the presently disclosed therapies may allow the practitioner to provide stimulation over a broader range of amplitudes, in at least some cases, the practitioner may not need to use the entire range. For example, as described above, the instances in which the patient may need to adjust the therapy may be significantly reduced when compared with standard SCS therapy because the presently disclosed therapy is relatively insensitive to patient position, posture and activity level. In addition to or in lieu of the foregoing effect, the amplitude of the signals applied in accordance with the presently disclosed techniques may be lower than the amplitude associated with standard SCS because the presently disclosed techniques may target neurons that are closer to the surface of the spinal cord. For example, it is believed that the nerve fibers associated with low back pain enter the spinal cord between T9 and T12(inclusive), and are thus close to the spinal cord surface at these vertebral locations.

Accordingly, the strength of the therapeutic spinal (e.g., the current amplitude) can be modest because the signal need not penetrate through a significant depth of spinal cord tissue to have the intended effect. Such low amplitude signals can have a reduced (or zero) tendency for triggering side effects, such as unwanted sensory and/or motor responses. Such low amplitude signals can also reduce the power required by the implanted pulse generator, and can therefore extend the battery life and the associated time between recharging and/or replacing the battery.

Yet another expected benefit of providing therapy in accordance with the foregoing parameters is that the practitioner need not implant the lead with the same level of precision as is typically required for standard SCS lead placement. For example, while the foregoing results were identified for patients having two leads (one positioned on either side of the spinal cord midline), it is expected that patients will receive the same or generally similar pain relief with a single lead placed at the midline. Accordingly, the practitioner may need to implant only one lead, rather than two. It is still further expected that the patient may receive pain relief on one side of the body when the lead is positioned offset from the spinal cord midline in the opposite direction. Thus, even if the patient has bilateral pain, e.g., with pain worse on one side than the other, the patient's pain can be addressed with a single implanted lead. Still further, it is expected that the lead position can vary laterally from the spinal cord midline to 3-4mm. away from midline (e.g., out to the dorsal root entry zone or DREZ). Yet further, it is expected that the lead (or more particularly, the active electrode or electrodes on the lead) can be positioned at any of a variety of axial locations in a range of one to two vertebral bodies while still providing effective treatment. Accordingly, the practitioner's selected implant site need not be identified or located as precisely as it is for standard SCS procedures (axially and/or laterally), while still producing significant patient benefits. This in turn can reduce the amount of time required to implant the lead, and can give the practitioner greater flexibility when implanting the lead. For example, if the patient has scar tissue or another impediment at a preferred implant site, the practitioner can locate the lead elsewhere and still obtain beneficial results.

Still another expected benefit, which can result from the foregoing observed insensitivities to lead placement and signal amplitude, is that the need for conducting a mapping procedure at the time the lead is implanted may be significantly reduced or eliminated. This is an advantage for both the patient and the practitioner because it reduces the amount of time and effort required to establish an effective therapy regimen. In particular, standard SCS therapy typically requires that the practitioner adjust the position of the lead and the amplitude of the signals delivered by the lead, while the patient is in the operating room reporting whether or not pain reduction is achieved. Because the presently disclosed techniques are relatively insensitive to lead position and amplitude, the mapping process can be eliminated entirely. Instead, the practitioner can place the lead at a selected vertebral location (e.g., T9-T12) and apply the stimulation at a preselected amplitude (e.g., 1 to 2 mA), with significantly reduced or eliminated trial-and-error optimization. In addition to or in lieu of the foregoing effect, the practitioner can, in at least some embodiments, provide effective therapy to the patient with a simple bipole arrangement of electrodes, as opposed to a tripole or other more complex arrangement that is used in existing systems to steer or otherwise direct therapeutic signals. In light of the foregoing effect(s), it is expected that the time required to complete a patient lead implant procedure and select stimulation parameters can be reduced by a factor of two or more, in particular embodiments. As a result, the practitioner can treat more patients per day, and the patients can more quickly engage in activities without pain.

The foregoing effect(s) can extend not only to the mapping procedure conducted at the practitioner's facility, but also to the subsequent trial period. In particular, patients receiving

standard SCS treatment typically spend a week after receiving a lead implant during which they adjust the amplitude applied to the lead in an attempt to establish suitable amplitudes for any of a variety of patient positions and patient activities. Because embodiments of the presently disclosed therapy are relatively insensitive to patient position and activity level, the need for this trial and error period can be reduced or eliminated.

Still another expected benefit associated with embodiments of the presently disclosed treatment is that the treatment may be less susceptible to patient habituation. In particular, it is expected that in at least some cases, the high frequency signal applied to the patient can produce an asynchronous neural response, as is disclosed in co-pending U.S. provisional application 61/171,190, assigned to the assignee of the present invention. The asynchronous response may be less likely to produce habituation than a synchronous response, which can result from lower frequency stimulation.

Yet another feature of embodiments of the foregoing therapy is that they can include applying the same waveform to all active electrodes simultaneously. For example, if two electrodes on an implanted lead body are active, both electrodes receive a positive pulse at time T**1** and both receive a negative pulse at time T**2**. In addition, due to the high frequency of the waveform, the adjacent tissue may perceive the waveform as a pseudo steady state signal. As a result of either or both of the foregoing effects, tissue adjacent both electrodes may be beneficially affected. This is unlike standard SCS waveforms for which one electrode is consistently cathodic and another is consistently anodic.

In any of the foregoing embodiments, aspects of the therapy provided to the patient may be varied within or outside the parameters used during the clinical testing described above, while still obtaining beneficial results for patients suffering from chronic low back pain. For example, the location of the lead body (and in particular, the lead body electrodes) can be varied over the significant lateral and/or axial ranges described above. Other characteristics of the applied signal can also be varied. For example, as described above, the signal can be delivered at a frequency of from about 1.5 kHz to about 100 kHz, and in particular embodiments, from about 1.5 kHz to about 50 kHz. In more particular embodiments, the signal can be provided at frequencies of from about 3 kHz to about 20 kHz, or from about 5 kHz to about 15 kHz, or from about 3 kHz to about 10 kHz. The amplitude of the signal can range from about 0.1 mA to about 20 mA in a particular embodiment, and in further particular embodiments, can range from about 0.5 mA to about 10 mA, or about 0.5 mA to about 4 mA, or about 0.5 mA to about 2.5 mA. The pulse width (e.g., for just the cathodic phase of the pulses) can vary from about 10 microseconds to about 333 microseconds. In further particular embodiments, the pulse width can range from about 25 microseconds to about 166 microseconds, or from about 33 microseconds to about 100 microseconds, or from about 50 microseconds to about 166 microseconds. The specific values selected for the foregoing parameters may vary from patient to patient and/or from indication to indication and/or on the basis of the selected vertebral location. In addition, the methodology may make use of other parameters, in addition to or in lieu of those described above, to monitor and/or control patient therapy. For example, in cases for which the pulse generator includes a constant voltage arrangement rather than a constant current arrangement, the current values described above may be replaced with corresponding voltage values.

In at least some embodiments, it is expected that the foregoing amplitudes will be suprathreshold. It is also expected that, in at least some embodiments, the neural response to the foregoing signals will be asynchronous, as described above. Accordingly, the frequency of the signal can be selected to be higher (e.g., between two and ten times higher) than the refractory period of the target neurons at the patient's spinal cord, which in at least some embodiments is expected to produce an asynchronous response.

Patients can receive multiple signals in accordance with still further embodiments of the disclosure. For example, patients can receive two or more signals, each with different signal delivery parameters. In one particular example, the signals are interleaved with each other. For instance, the patient can receive 5 kHz pulses interleaved with 10 kHz pulses. In other embodiments, patients can receive sequential "packets" of pulses at different frequencies, with each packet having a duration of less than one second, several seconds, several minutes, or longer depending upon the particular patient and indication.

In still further embodiments, the duty cycle may be varied from the 50% -100% range of values described above, as can the lengths of the on/off periods. For example, it has been observed that patients can have therapeutic effects (e.g., pain reduction) that persist for significant periods after the stimulation has been halted. In particular examples, the beneficial effects can persist for 10-20 minutes in some cases, and up to an hour in others. Accordingly, the simulator can be programmed to halt stimulation for periods of up to an hour, with appropriate allowances for the time necessary to re-start the beneficial effects. This arrangement can significantly reduce system power consumption, compared to systems with higher duty cycles, and compared to systems that have shorter on/off periods.

Representative Lead Designs

FIG. **16** is a partially schematic illustration of a lead **1610** having first and second contacts C**21**, C**22** positioned in accordance with particular embodiments of the disclosure. The lead **1610** can include at least two first contacts C**21** and at least two second contacts C**22** to support bipolar stimulation via each contact grouping. In one aspect of this embodiment, the lead **1610** can have an overall length L (over which active contacts are positioned) that is longer than that of typical leads. In particular, the length L can be sufficient to position first contacts C**21** at one or more vertebral locations, and position the second contacts C**22** at another vertebral location that is spaced apart from the first and that is superior the first. For example, the first contacts C**21** may be positioned at vertebral levels T9-T12 to treat low back pain, and the second contacts C**22** may be positioned at superior vertebral locations (e.g., cervical locations) to treat arm pain. Pulses may be applied to both groups of contacts in accordance with several different arrangements. For example pulses provided to one group may be interleaved with pulses applied to the other, or the same signal may be rapidly switched from one group to the other. In other embodiments, the signals applied to individual contacts, pairs of contacts, and/or contacts in different groups may be multiplexed in other manners. In any of these embodiments, each of the contacts C**21**, C**22** can have an appropriately selected surface area, e.g., in the range of from about 5 mm^2 to about 20 mm^2, and in particular embodiments, from about 10 mm^2 to about 15 mm^2. Individual contacts on a given lead can have different surface area values, within the foregoing ranges, than neighboring or other contacts of the lead, with values selected depending upon features including the vertebral location of the individual contact.

Another aspect of an embodiment of the lead **1610** shown in FIG. **16** is that the first contacts C**21** can have a significantly

wider spacing than is typically associated with standard SCS contacts. For example, the first contacts C**21** can be spaced apart by a distance S**11** that corresponds to between one and two vertebral bodies (typically 32-64 mm.). This increased spacing can reduce the complexity of the lead **1610**, and can still provide effective treatment to the patient because, as discussed above, the effectiveness of the presently disclosed therapy is relatively insensitive to the axial location of the signal delivery contacts. The second contacts C**22** can have a similar wide spacing when used to apply high frequency stimulation in accordance with the presently disclosed methodologies. However, in another embodiment, different portions of the lead **1610** can have contacts that are spaced apart by different distances. For example, if the patient receives high frequency pain suppression treatment via the first contacts C**21** at a first vertebral location, the patient can optionally receive low frequency, paresthesia-inducing signals at the second vertebral location via second contacts C**22** that are spaced apart by a distance S**12**. The distance S**12** can be smaller than the distance S**11** and, in particular embodiments, can be typical of contact spacings for standard SCS treatment, as these contacts may be used for providing such treatment. In still further embodiments, the inferior first contacts C**21** can have the close spacing S**12**, and the superior second contacts C**22** can have the wide spacing S**11**, depending upon patient indications and/or preferences. In still further embodiments, as noted above, contacts at both the inferior and superior locations can have the wide spacing, e.g., to support high frequency stimulation at multiple locations along the spinal cord. In other embodiments, the lead **1610** can include other arrangements of different contact spacings, depending upon the particular patient and indication.

In still further particular embodiments, for example, when the second contacts C**22** are to provide high frequency therapy in the manner of the first contacts C**21**, individual contacts C**22** can be electrically shorted to each other. This can provide benefits including increased field strength and/or reduced signal processing complexity. This system simplification results from the generally robust nature of the applied stimulation, including the ability to avoid current steering, which in turn avoids the need for individually addressable contacts.

In some cases, it may be desirable to adjust the distance between the inferior contacts C**21** and the superior contacts C**22**. For example, the lead **1610** can have a coil arrangement (like a telephone cord) or other length-adjusting feature that allows the practitioner to selectively vary the distance between the sets of contacts. In a particular aspect of this arrangement, the coiled portion of the lead can be located between the first contacts C**21** and the second contacts C**22**. In another embodiment, particularly suitable for the shorted contacts described above, the lead **1610** can be a single or multifilar coil, with selected sections insulated to form contacts at the remaining interstitial locations. This arrangement can be easy to design and manufacture, and can make use of different stencils to provide different contact spacings, depending upon specific patient applications. In addition to or in lieu of the foregoing effect, the coil arrangement can provide for greater maneuverability and facilitate the implantation process by eliminating ring electrodes and/or other rigid contacts. In other embodiments, other arrangements can be used to provide contact flexibility. For example, the contacts can be formed from a conductive silicone, e.g., silicone impregnated with a suitable loading of conductive material, such as platinum, iridium or another noble metal. In still further embodiments, aspects of the coil arrangement can be combined with ring or other types of contacts. For example, the superior portion of the lead **1610** can have a coil arrangement (to support greater flexibility at the distal end of the lead) and the inferior portion of the lead can include ring contacts. In any of these embodiments, the coil portion of the lead can include one or more single and/or multifilar arrangements.

Yet another feature of an embodiment of the lead shown in FIG. **16** is that individual contacts can each have the same current applied to them. For example, as discussed above, each of the contacts can simultaneously receive a cathodic pulse portion and can then each simultaneously receive an anodic pulse portion. In another embodiment, each contact can receive the cathodic pulse portion, and the implanted pulse generator (not visible in FIG. **16**) can serve as a return electrode. For example, the pulse generator can include a housing that serves as the return electrode, of the pulse generator can otherwise carry a return electrode that has a fixed position relative to the pulse generator. Accordingly, the stimulation provided by the active contacts can be unipolar stimulation, as opposed to the more typical bipolar stimulation associated with standard SCS treatments.

Representative Programmer Designs

The robust characteristics of the presently disclosed therapy techniques may enable other aspects of the overall system described above with reference to FIG. **1**A to be simplified. For example, the patient remote and the physician programmer can be simplified significantly because the need to change stimulation parameters can be reduced significantly or eliminated entirely. In particular, it is expected that in certain embodiments, once the lead is implanted, the patient can receive effective therapy while assuming a wide range of positions and engaging in a wide range of activities, without having to change the signal amplitude or other signal delivery parameters. As a result, the patient remote need not include any programming functions, but can instead include a simple on/off function (e.g., an on/off button or switch). The patient remote may also include an indicator (e.g., a light) that identifies when the pulse generator is active. This feature may be particularly useful in connection with the presently disclosed therapies because the patient will typically not feel a paresthesia, unless the system is configured and programmed to deliberately produce parasthesia in addition to the therapy signal. In particular embodiments, the physician programmer can be simplified in a similar manner, though in some cases, it may be desirable to maintain at least some level of programming ability at the physician programmer. Such a capability can allow the physician to select different contacts and/or other signal delivery parameters in the rare instances when the lead migrates or when the patient undergoes physiological changes (e.g., scarring) or lifestyle changes (e.g., new activities) that are so significant they require a change in the active contact(s) and/or other signal delivery parameters.

Representative Stimulation Locations and Indications

Many of the embodiments described above were described in the context of treating chronic, neuropathic low back pain with stimulation applied to the lower thoracic vertebrae (T9-T12). In other embodiments, stimulation signals having parameters (e.g., frequency, pulse width, amplitude, and/or duty cycle) generally similar to those described above can be applied to other patient locations to address other indications. For example, while the foregoing methodologies included applying stimulation at lateral locations ranging from the spinal cord midline to the DREZ, in other embodiments, the stimulation may be applied to the foramen region, laterally outward from the DREZ. In other embodiments, the stimulation may be applied to other spinal levels of the patient. For example, stimulation may be applied to the sacral region and

more particularly, the "horse tail" region at which the sacral nerves enter the sacrum. Urinary incontinence and fecal incontinence represent example indications that are expected to be treatable with stimulation applied at this location. In other embodiments, the stimulation may be applied to other thoracic vertebrae. For example, stimulation may be applied to thoracic vertebrae above T9. In a particular embodiment, stimulation may be applied to the T3-T6 region to treat angina. Stimulation can be applied to high thoracic vertebrae to treat pain associated with shingles. Stimulation may be applied to the cervical vertebrae to address chronic regional pain syndrome and/or total body pain, and may be used to replace neck surgery. Suitable cervical locations include vertebral levels C3-C7, inclusive. In other embodiments, stimulation may be applied to the occipital nerves, for example, to address migraine headaches.

As described above, stimulation in accordance with the foregoing parameters may also be applied to treat acute and/or chronic nociceptive pain. For example, stimulation in accordance with these parameters can be used during surgery to supplement and/or replace anesthetics (e.g., a spinal tap). Such applications may be used for tumor removal, knee surgery, and/or other surgical techniques. Similar techniques may be used with an implanted device to address post-operative pain, and can avoid the need for topical lidocaine. In still further embodiments, stimulation in accordance with the foregoing parameters can be used to address other peripheral nerves. For example, stimulation can be applied directly to peripheral nerves to address phantom limb pain.

Representative Therapy Parameters

Nevro Corporation, the assignee of the present application, has conducted a multi-site clinical study during which multiple patients were first treated with conventional spinal cord stimulation (SCS) techniques, and then with newly developed techniques that are disclosed further below. Multiple embodiments of the newly developed techniques and/or therapies are referred to collectively herein as presently disclosed techniques and/or presently disclosed therapies.

Prior to the clinical study, selected patients were identified as suffering from primary chronic low back pain (e.g., neuropathic pain, and/or nociceptive pain, and/or other types of pain, depending upon the patient), either alone or in combination with pain affecting other areas, typically the patient's leg. In all cases, the low back pain was dominant. During the study, the patients were outfitted with two leads, each implanted in the spinal region in a manner generally similar to that shown in FIG. **1**A. One lead was implanted on one side of the spinal cord midline, and the other lead was implanted on the other side of the spinal cord midline. FIG. **8** is a cross-sectional illustration of the spinal cord **191** and an adjacent vertebra **895** (based generally on information from Crossman and Neary, "Neuroanatomy," 1995 (published by Churchill Livingstone)), along with the locations at which leads **810** were implanted in a representative patient. The spinal cord **191** is situated between a ventrally located ventral body **896** and the dorsally located transverse process **898** and spinous process **897**. Arrows V and D identify the ventral and dorsal directions, respectively. The spinal cord **191** itself is located within the dura mater **899**, which also surrounds portions of the nerves exiting the spinal cord **191**, including the dorsal roots **893** and dorsal root ganglia **894**. The leads **810** were positioned just off the spinal cord midline **889** (e.g., about 1 mm. offset) in opposing lateral directions so that the two leads **810** were spaced apart from each other by about 2 mm.

Patients with the leads **810** located as shown in FIG. **8** initially had the leads positioned at vertebral levels T7-T8. This location is typical for standard SCS treatment of low back pain because it has generally been the case that at lower (inferior) vertebral levels, standard SCS treatment produces undesirable side effects, and/or is less efficacious. Such side effects include unwanted muscle activation and/or pain. Once the leads **810** were implanted, the patients received standard SCS treatment for a period of five days. This treatment included stimulation at a frequency of less than 1500 Hz (e.g., 60-80 Hz), a pulse width of 100-200 psec, and a duty cycle of 100%. The amplitude of the signal (e.g., the current amplitude) was varied from about 3mA to about 10 mA. The amplitude was initially established during the implant procedure. The amplitude was then changed by the patient on an as-desired basis during the course of the study, as is typical for standard SCS therapies.

After the patient completed the standard SCS portion of the study, the patient then received stimulation in accordance with the presently disclosed techniques. One aspect of these techniques included moving the leads **810** inferiorly, so as to be located at vertebral levels T9, T10, T11, and/or T12. After the leads **810** were repositioned, the patient received therapeutic stimulation at a frequency of from about 3kHz to about 10 kHz. In particular cases, the therapy was applied at 8 kHz, 9 kHz or 10KHz. These frequencies are significantly higher than the frequencies associated with standard SCS, and accordingly, stimulation at these and other representative frequencies (e.g., from about 1.5 kHz to about 100 kHz) is occasionally referred to herein as high frequency stimulation. The stimulation was applied generally at a duty cycle of from about 50% to about 100%, with the stimulation signal on for a period of from about 1 msec. to about 2 seconds, and off for a period of from about 1 msec. to about 1.5 seconds. The width of the applied pulses was about 30-35 μsec., and the amplitude generally varied from about 1 mA to about 4 mA (nominally about 2.5 mA). Stimulation in accordance with the foregoing parameters was typically applied to the patients for a period of about four days during the clinical study.

FIGS. **9-13**A graphically illustrate summaries of the clinical results obtained by testing patients in accordance with the foregoing parameters. FIG. **9** is a bar chart illustrating the patients' Visual Analog Scale (VAS) pain score for a variety of conditions. The scores indicated in FIG. **9** are for overall pain. As noted above, these patients suffered primarily from low back pain and accordingly, the pain scores for low back pain alone were approximately the same as those shown in FIG. **9**. Each of the bars represents an average of the values reported by the multiple patients involved in this portion of the study. Bars **901** and **902** illustrate a baseline pain level of 8.7 for the patients without the benefit of medication, and a baseline level of 6.8 with medication, respectively. After receiving a lead implant on day zero of the study, and initiating high frequency stimulation in accordance with the foregoing parameters, patients reported an average pain score of about 4.0, as represented by bar **903**. Over the course of the next three days, (represented by bars **904-913**) the patients recorded pain levels in a diary every morning, midday and evening, as indicated by the correspondingly labeled bars in FIG. **9**. In addition, pain levels were recorded daily by the local center research coordinator on case report forms (CRFs) as indicated by the correspondingly labeled bars in FIG. **9**. During this time period, the patients' average pain score gradually decreased to a reported minimum level of about 2.2 (represented by bars **912** and **913**).

For purposes of comparison, bar **914** illustrates the pain score for the same patients receiving standard SCS therapy earlier in the study. Bar **914** indicates that the average pain value for standard SCS therapy was 3.8. Unlike the results of the presently disclosed therapy, standard SCS therapy tended

to produce relatively flat patient pain results over the course of several days. Comparing bars **913** and **914**, the clinical results indicate that the presently disclosed therapy reduced pain by 42% when compared with standard SCS therapy.

Other pain indices indicated generally consistent results. On the Oswestry Disability Index, average scores dropped from a baseline value of 54 to a value of 33, which is equivalent to a change from "severe disability" to "moderate disability".

Patients' global improvement scores ranked 1.9 on a scale of 1 ("very much improved") to 7 ("very much worse").

In addition to obtaining greater pain relief with the presently disclosed therapy than with standard SCS therapy, patients experienced other benefits as well, described further below with reference to FIGS. **10-12**. FIG. **10** is a bar chart illustrating the number of times per day that the patients initiated stimulation changes. Results are illustrated for standard SCS therapy (bar **1001**) and the presently disclosed therapy (bar **1002**). The patient-initiated stimulation changes were generally changes in the amplitude of the applied signal, and were initiated by the patient via an external stimulator or remote, such as was described above with reference to FIG. **1**A. Patients receiving standard SCS therapy initiated changes to the stimulation parameters an average of 44 times per day. The initiated changes were typically triggered when the patient changed position, activity level, and/or activity type, and then experienced a reduction in pain relief and/or an unpleasant, uncomfortable, painful, unwanted or unexpected sensation from the therapeutic signal. Patients receiving the presently disclosed therapy did not change the stimulation parameters at all, except at the practitioners' request. In particular, the patients did not change signal amplitude to avoid painful stimulation. Accordingly, FIG. **10** indicates that the presently disclosed therapy is significantly less sensitive to lead movement, patient position, activity level and activity type than is standard SCS therapy.

FIG. **11** is a bar graph illustrating activity scores for patients receiving the presently disclosed therapy. The activity score is a quality of life score indicating generally the patients' level of satisfaction with the amount of activity that they are able to undertake. As indicated in FIG. **11**, bar **1101** identifies patients having a score of 1.9 (e.g., poor to fair) before beginning therapy. The score improved over time (bars **1102-1104**) so that at the end of the second day of therapy, patients reported a score of nearly 3 (corresponding to a score of "good"). It is expected that in longer studies, the patients' score may well improve beyond the results shown in FIG. **11**. Even the results shown in FIG. **11**, however, indicate a 53% improvement (compared to baseline) in the activity score for patients receiving the presently disclosed therapy over a three day period. Anecdotally, patients also indicated that they were more active when receiving the presently disclosed therapy than they were when receiving standard SCS therapy. Based on anecdotal reports, it is expected that patients receiving standard SCS therapy would experience only a 10% - 15% improvement in activity score over the same period of time.

FIG. **12** is a bar chart illustrating changes in activity score for patients receiving the presently disclosed therapy and performing six activities: standing, walking, climbing, sitting, riding in a car, and eating. For each of these activities, groups of bars (with individual groups identified by reference numbers **1201**, **1202**, **1203** . . . **1206**) indicate that the patients' activity score generally improved over the course of time. These results further indicate that the improvement in activity was broad-based and not limited to a particular activity. Still further, these results indicate a significant level of improvement in each activity, ranging from 30% for eating to 80% - 90% for standing, walking and climbing stairs. Anecdotally, it is expected that patients receiving standard SCS treatment would experience only about 10% - 20% improvement in patient activity. Also anecdotally, the improvement in activity level was directly observed in at least some patients who were hunched over when receiving standard SCS treatment, and were unable to stand up straight. By contrast, these patients were able to stand up straight and engage in other normal activities when receiving the presently disclosed therapy.

Based on additional patient feedback, every one of the tested patients who received the presently disclosed therapy at the target location (e.g., who received the presently disclosed therapy without the lead migrating significantly from its intended location) preferred the presently disclosed therapy to standard SCS therapy. In addition, irrespective of the level of pain relief the patients received, 88% of the patients preferred the presently disclosed therapy to standard SCS therapy because it reduced their pain without creating paresthesia. This indicates that while patients may prefer paresthesia to pain, a significant majority prefer no sensation to both pain and paresthesia. This result, obtained via the presently disclosed therapy, is not available with standard SCS therapies that are commonly understood to rely on paresthesia (i.e., masking) to produce pain relief.

Still further, anecdotal data indicate that patients receiving the presently disclosed therapy experienced less muscle capture than they experienced with standard SCS. In particular, patients reported a lack of spasms, cramps, and muscle pain, some or all of which they experienced when receiving standard SCS. Patients also reported no interference with volitional muscle action, and instead indicated that they were able to perform motor tasks unimpeded by the presently disclosed therapy. Still further, patients reported no interference with other sensations, including sense of touch (e.g., detecting vibration), temperature and proprioception. In most cases, patients reported no interference with nociceptive pain sensation. However, in some cases, patients reported an absence of incision pain (associated with the incision used to implant the stimulation lead) or an absence of chronic peripheral pain (associated with arthritis). Accordingly, in particular embodiments, aspects of the currently disclosed techniques may be used to address nociceptive pain, including acute peripheral pain, and/or chronic peripheral pain, as will be discussed in greater detail later.

FIG. **13**A is a bar chart indicating the number of successful therapeutic outcomes as a function of the location (indicated by vertebral level) of the active contacts on the leads that provided the presently disclosed therapy. In some cases, patients obtained successful outcomes when stimulation was provided at more than one vertebral location. As indicated in FIG. **13**A, successful outcomes were obtained over a large axial range (as measured in a superior-inferior direction along the spine) from vertebral bodies T9 to T12. This is a surprising result in that it indicates that while there may be a preferred target location (e.g., around T10), the lead can be positioned at a wide variety of locations while still producing successful results. In particular, neighboring vertebral bodies are spaced apart from each other by approximately 32millimeters (depending on specific patient anatomy), and so successful results were obtained over a broad range of four vertebral bodies (about 128 mm.) and a narrower range of one to two vertebral bodies (about 32-64 mm.). By contrast, standard SCS data generally indicate that the therapy may change from effective to ineffective with a shift of as little as 1 mm. in lead location. As will be discussed in greater detail later, the flex-

ibility and versatility associated with the presently disclosed therapy can produce significant benefits for both the patient and the practitioner.

FIGS. **13**B and **13**C are flow diagrams illustrating methods for treating patients in accordance with particular embodiments of the present disclosure. FIG. **13**B illustrates a method **1300** that includes implanting a signal generator in a patient (block **1310**). The signal generator can be implanted at the patient's lower back or other suitable location. The method **1300** further includes implanting a signal delivery device (e.g., a lead, paddle or other suitable device) at the patient's spinal cord region (block **1320**). This portion of the method can in turn include implanting the device at a vertebral level ranging from T9 to T12, inclusive (block **1321**), and at a lateral location ranging from the spinal cord midline to the DREZ, inclusive (block **1322**). At block **1330**, the method includes applying a high frequency waveform, via the signal generator and the signal delivery device. In particular examples, the frequency of the signal (or at least a portion of the signal) can be from about 1.5 kHz to about 100 kHz, or from about 1.5 kHz to about 50 kHz., or from about 3 kHz to about 20 kHz, or from about 5 kHz to about 15 kHz, or from about 3 kHz to about 10 kHz. The method **1300** further includes blocking, suppressing, inhibiting or otherwise reducing the patient's pain, e.g., low back pain (block **1340**). This portion of the method can in turn include reducing pain without unwanted sensory effects and/or limitations (block **1341**), and/or without motor effects (block **1342**). For example, block **1341** can include reducing or eliminating pain without reducing patient perception of other sensations, and/or without triggering additional pain. Block **1342** can include reducing or eliminating pain without triggering muscle action and/or without interfering with motor signal transmission.

FIG. **13**C illustrates a method **1301** that includes features in addition to those described above with reference to FIG. **13**B. For example, the process of applying a high frequency waveform (block **1330**) can include doing so over a wide amplitude range (e.g., less than 1 mA to about 8 mA) without creating unwanted side effects, such as undesirable sensations and/or motor interference (block **1331**). In another embodiment, the process of applying a high frequency waveform can include applying the waveform at a fixed amplitude (block **1332**). As described further later, each of these aspects can provide patient and/or practitioner benefits.

The process of blocking, suppressing or otherwise reducing patient pain (block **1340**) can include doing so without creating paresthesia (block **1343**), or in association with a deliberately generated paresthesia (block **1344**). As noted above, clinical results indicate that most patients prefer the absence of paresthesia to the presence of paresthesia, e.g., because the sensation of paresthesia may change to an uncomfortable or painful sensation when the patient changes position and/or adjusts the signal amplitude. However, in some cases, patients may prefer the sensation of paresthesia, and so can have the option of receiving it. In other cases, paresthesia may be used by the practitioner for site selection (e.g., to determine the location at which active electrodes are positioned). In addition to the above, reducing patient pain can include doing so with relative insensitivity to patient attributes that standard SCS is normally highly sensitive to (block **1345**). These attributes can include patient movement (block **1346**) and/or patient position (block **1347**).

FIG. **14** is a schematic diagram (based on Linderoth and Foreman, "Mechanisms of Spinal Cord Stimulation in Painful Syndromes: Role of Animal Models," Pain Medicine, Vol. 51, 2006) illustrating an expected mechanism of action for standard SCS treatment, along with potential mechanisms of action for therapy provided in accordance with embodiments of the present technology. When a peripheral nerve is injured, it is believed that the Aδ and C nociceptors provide an increased level of excitatory transmitters to second order neurons at the dorsal horn of the spinal cord. Standard SCS therapy, represented by arrow **1401**, is expected to have two effects. One effect is an orthodromic effect transmitted along the dorsal column to the patient's brain and perceived as paresthesia. The other is an antidromic effect that excites the interneuron pool, which in turn inhibits inputs to the second order neurons.

One potential mechanism of action for the presently disclosed therapy is represented by arrow **1410**, and includes producing an incomplete conduction block (e.g., an incomplete block of afferent and/or efferent signal transmission) at the dorsal root level. This block may occur at the dorsal column, dorsal horn, and/or dorsal root entry zone, in addition to or in lieu of the dorsal root. In any of these cases, the conduction block is selective to and/or preferentially affects the smaller Aδ and/or C fibers and is expected to produce a decrease in excitatory inputs to the second order neurons, thus producing a decrease in pain signals supplied along the spinal thalamic tract.

Another potential mechanism of action (represented by arrow **1420** in FIG. **14**) includes more profoundly activating the interneuron pool and thus increasing the inhibition of inputs into the second order neurons. This can, in effect, potentially desensitize the second order neurons and convert them closer to a normal state before the effects of the chronic pain associated signals have an effect on the patient.

The foregoing mechanisms of action are identified here as possible mechanisms of action that may account for the foregoing clinical results. In particular, these mechanisms of action may explain the surprising result that pain signals transmitted by the small, slow Aδ and C fibers may be inhibited without affecting signal transmission along the larger, faster Aβ fibers. This is contrary to the typical results obtained via standard SCS treatments, during which stimulation signals generally affect AR fibers at low amplitudes, and do not affect Aδ and C fibers until the signal amplitude is so high as to create pain or other unwanted effects transmitted by the Aβ fibers. However, aspects of the present disclosure need not be directly tied to such mechanisms. In addition, aspects of both the two foregoing proposed mechanisms may in combination account for the observed results in some embodiments, and in other embodiments, other mechanisms may account for the observed results, either alone or in combination with either one of the two foregoing mechanisms. One such mechanism includes an increased ability of high frequency stimulation (compared to standard SCS stimulation) to penetrate through the cerebral spinal fluid (CSF) around the spinal cord.

Another such mechanism is the expected reduction in impedance presented by the patient's tissue to high frequencies, as compared to standard SCS frequencies. Although the higher frequencies associated with the presently disclosed techniques may initially appear to require more power than conventional SCS techniques, the signal amplitude may be reduced when compared to SCS values (due to improved signal penetration) and/or the duty cycle may be reduced (due to persistence effects described later). Accordingly, the presently disclosed techniques can result in a net power savings when compared with standard SCS techniques.

Expected Benefits Associated With Certain Embodiments

Certain of the foregoing embodiments can produce one or more of a variety of advantages, for the patient and/or the practitioner, when compared with standard SCS therapies. Some of these benefits were described above. For example, as

described above, the patient can experience a significant pain reduction that is largely independent of the patient's movement and position. In particular, the patient can assume a variety of positions and/or undertake a variety of movements associated with activities of daily living and/or other activities, without the need to adjust the parameters in accordance with which the therapy is applied to the patient (e.g., the stimulation amplitude). This result can greatly simplify the patient's life and reduce the effort required by the patient to experience pain relief while engaging in a variety of activities.

The foregoing result can have particular advantages for patients who otherwise experience significant sleep disturbances. Such patients may establish a stimulation parameter at a particular level when lying prone. When the patient rolls over while sleeping, the patient may experience a significant enough change in the pain reduction provided by standard SCS treatments to cause the patient to wake. In many cases, the patient may additionally experience pain generated by the stimulation signal itself, on top of the pain the stimulation signal is intended to reduce. With the presently disclosed techniques, by contrast, this undesirable effect can be avoided. FIGS. **15**A and **15**B illustrate the average effect on sleep for clinical patients receiving the presently disclosed therapy. FIG. **15**A illustrates the reduction in patient disturbances, and

FIG. **15**B illustrates the increase in number of hours slept. In other embodiments, the patient may be able to perform other tasks with reduced pain. For example, patients may drive without having to adjust the therapy level provided by the implanted device. Accordingly, the presently disclosed therapy may be more readily used by patients in such situations and/or other situations that improve the patients' quality of life.

Another benefit observed during the clinical studies described above is that when the patient does experience a change in the therapy level, it is a gradual change. This is unlike typical changes associated with conventional SCS therapies. With conventional SCS therapies, if a patient changes position or changes an amplitude setting, the patient can experience a sudden onset of pain, often described by patients as unbearable. By contrast, patients in the clinical study described above, when treated with the presently disclosed therapy, reported a gradual onset of pain when signal amplitude was increased beyond a threshold level, with the pain described as gradually becoming uncomfortable. One patient described a sensation akin to a cramp coming on, but never fully developing. This significant difference in patient response to changes in signal delivery parameters can allow the patient to more freely change stimulation parameters and/or posture when desired, without fear of creating an immediately painful effect.

Another observation from the clinical studies described above is that the amplitude "window" between the onset of effective therapy and the onset of pain or discomfort is relatively broad, and in particular, broader than it is for standard SCS treatment. For example, during standard SCS treatment, the patient typically experiences a pain reduction at a particular amplitude, and begins experiencing pain from the therapeutic signal (which may have a sudden onset, as described above) at about 1.6 times that amplitude. This corresponds to a dynamic range of about 1.6. In addition, patients receiving standard SCS stimulation typically wish to receive the stimulation at close to the pain onset level because the therapy is often most effective at that level. Accordingly, patient preferences may further reduce the effective dynamic range. By contrast, therapy in accordance with the presently disclosed embodiments resulted in patients obtaining pain relief at 1 mA or less, and not encountering pain or muscle capture until the applied signal had an amplitude of 4 mA, and in some cases up to about 8 mA, corresponding to a much larger dynamic range. Even at the forgoing amplitude levels, the pain experienced by the patients was significantly less that that associated with standard SCS pain onset. An expected advantage of this result is that the patient and practitioner can have significantly wider latitude in selecting an appropriate therapy amplitude with the presently disclosed methodology than with standard SCS methodologies. For example, the practitioner can increase the signal amplitude in an effort to affect more (e.g., deeper) fibers at the spinal cord, without triggering unwanted side effects. The existence of a wider amplitude window may also contribute to the relative insensitivity of the presently disclosed therapy to changes in patient posture and/or activity. For example, if the relative position between the implanted lead and the target neural population changes as the patient moves, the effective strength of the signal when it reaches the target neural population may also change. When the target neural population is insensitive to a wider range of signal strengths, this effect can in turn allow greater patient range of motion without triggering undesirable side effects.

Although the presently disclosed therapies may allow the practitioner to provide stimulation over a broader range of amplitudes, in at least some cases, the practitioner may not need to use the entire range. For example, as described above, the instances in which the patient may need to adjust the therapy may be significantly reduced when compared with standard SCS therapy because the presently disclosed therapy is relatively insensitive to patient position, posture and activity level. In addition to or in lieu of the foregoing effect, the amplitude of the signals applied in accordance with the presently disclosed techniques may be lower than the amplitude associated with standard SCS because the presently disclosed techniques may target neurons that are closer to the surface of the spinal cord. For example, it is believed that the nerve fibers associated with low back pain enter the spinal cord between T9 and T12(inclusive), and are thus close to the spinal cord surface at these vertebral locations.

Accordingly, the strength of the therapeutic spinal (e.g., the current amplitude) can be modest because the signal need not penetrate through a significant depth of spinal cord tissue to have the intended effect. Such low amplitude signals can have a reduced (or zero) tendency for triggering side effects, such as unwanted sensory and/or motor responses. Such low amplitude signals can also reduce the power required by the implanted pulse generator, and can therefore extend the battery life and the associated time between recharging and/or replacing the battery.

Yet another expected benefit of providing therapy in accordance with the foregoing parameters is that the practitioner need not implant the lead with the same level of precision as is typically required for standard SCS lead placement. For example, while the foregoing results were identified for patients having two leads (one positioned on either side of the spinal cord midline), it is expected that patients will receive the same or generally similar pain relief with a single lead placed at the midline. Accordingly, the practitioner may need to implant only one lead, rather than two. It is still further expected that the patient may receive pain relief on one side of the body when the lead is positioned offset from the spinal cord midline in the opposite direction. Thus, even if the patient has bilateral pain, e.g., with pain worse on one side than the other, the patient's pain can be addressed with a single implanted lead. Still further, it is expected that the lead

position can vary laterally from the spinal cord midline to 3-4 mm. away from midline (e.g., out to the dorsal root entry zone or DREZ). Yet further, it is expected that the lead (or more particularly, the active electrode or electrodes on the lead) can be positioned at any of a variety of axial locations in a range of one to two vertebral bodies while still providing effective treatment. Accordingly, the practitioner's selected implant site need not be identified or located as precisely as it is for standard SCS procedures (axially and/or laterally), while still producing significant patient benefits. This in turn can reduce the amount of time required to implant the lead, and can give the practitioner greater flexibility when implanting the lead. For example, if the patient has scar tissue or another impediment at a preferred implant site, the practitioner can locate the lead elsewhere and still obtain beneficial results.

Still another expected benefit, which can result from the foregoing observed insensitivities to lead placement and signal amplitude, is that the need for conducting a mapping procedure at the time the lead is implanted may be significantly reduced or eliminated. This is an advantage for both the patient and the practitioner because it reduces the amount of time and effort required to establish an effective therapy regimen. In particular, standard SCS therapy typically requires that the practitioner adjust the position of the lead and the amplitude of the signals delivered by the lead, while the patient is in the operating room reporting whether or not pain reduction is achieved. Because the presently disclosed techniques are relatively insensitive to lead position and amplitude, the mapping process can be eliminated entirely. Instead, the practitioner can place the lead at a selected vertebral location (e.g., T9-T12) and apply the stimulation at a preselected amplitude (e.g., 1 to 2 mA), with significantly reduced or eliminated trial-and-error optimization. In addition to or in lieu of the foregoing effect, the practitioner can, in at least some embodiments, provide effective therapy to the patient with a simple bipole arrangement of electrodes, as opposed to a tripole or other more complex arrangement that is used in existing systems to steer or otherwise direct therapeutic signals. In light of the foregoing effect(s), it is expected that the time required to complete a patient lead implant procedure and select stimulation parameters can be reduced by a factor of two or more, in particular embodiments. As a result, the practitioner can treat more patients per day, and the patients can more quickly engage in activities without pain.

The foregoing effect(s) can extend not only to the mapping procedure conducted at the practitioner's facility, but also to the subsequent trial period. In particular, patients receiving standard SCS treatment typically spend a week after receiving a lead implant during which they adjust the amplitude applied to the lead in an attempt to establish suitable amplitudes for any of a variety of patient positions and patient activities. Because embodiments of the presently disclosed therapy are relatively insensitive to patient position and activity level, the need for this trial and error period can be reduced or eliminated.

Still another expected benefit associated with embodiments of the presently disclosed treatment is that the treatment may be less susceptible to patient habituation. In particular, it is expected that in at least some cases, the high frequency signal applied to the patient can produce an asynchronous neural response, as is disclosed in co-pending U.S. provisional application 61/171,190, assigned to the assignee of the present invention. The asynchronous response may be less likely to produce habituation than a synchronous response, which can result from lower frequency stimulation.

Yet another feature of embodiments of the foregoing therapy is that they can include applying the same waveform to all active electrodes simultaneously. For example, if two electrodes on an implanted lead body are active, both electrodes receive a positive pulse at time T1 and both receive a negative pulse at time T2. In addition, due to the high frequency of the waveform, the adjacent tissue may perceive the waveform as a pseudo steady state signal. As a result of either or both of the foregoing effects, tissue adjacent both electrodes may be beneficially affected. This is unlike standard SCS waveforms for which one electrode is consistently cathodic and another is consistently anodic.

In any of the foregoing embodiments, aspects of the therapy provided to the patient may be varied within or outside the parameters used during the clinical testing described above, while still obtaining beneficial results for patients suffering from chronic low back pain. For example, the location of the lead body (and in particular, the lead body electrodes) can be varied over the significant lateral and/or axial ranges described above. Other characteristics of the applied signal can also be varied. For example, as described above, the signal can be delivered at a frequency of from about 1.5 kHz to about 100 kHz, and in particular embodiments, from about 1.5 kHz to about 50 kHz. In more particular embodiments, the signal can be provided at frequencies of from about 3 kHz to about 20 kHz, or from about 5 kHz to about 15 kHz, or from about 3kHz to about 10 kHz. The amplitude of the signal can range from about 0.1 mA to about 20 mA in a particular embodiment, and in further particular embodiments, can range from about 0.5 mA to about 10 mA, or about 0.5 mA to about 4 mA, or about 0.5 mA to about 2.5 mA. The pulse width (e.g., for just the cathodic phase of the pulses) can vary from about 10 microseconds to about 333 microseconds. In further particular embodiments, the pulse width can range from about 25 microseconds to about 166microseconds, or from about 33 microseconds to about 100 microseconds, or from about 50 microseconds to about 166 microseconds. The specific values selected for the foregoing parameters may vary from patient to patient and/or from indication to indication and/or on the basis of the selected vertebral location. In addition, the methodology may make use of other parameters, in addition to or in lieu of those described above, to monitor and/or control patient therapy. For example, in cases for which the pulse generator includes a constant voltage arrangement rather than a constant current arrangement, the current values described above may be replaced with corresponding voltage values.

In at least some embodiments, it is expected that the foregoing amplitudes will be suprathreshold. It is also expected that, in at least some embodiments, the neural response to the foregoing signals will be asynchronous, as described above. Accordingly, the frequency of the signal can be selected to be higher (e.g., between two and ten times higher) than the refractory period of the target neurons at the patient's spinal cord, which in at least some embodiments is expected to produce an asynchronous response.

Patients can receive multiple signals in accordance with still further embodiments of the disclosure. For example, patients can receive two or more signals, each with different signal delivery parameters. In one particular example, the signals are interleaved with each other. For instance, the patient can receive 5 kHz pulses interleaved with 10 kHz pulses. In other embodiments, patients can receive sequential "packets" of pulses at different frequencies, with each packet having a duration of less than one second, several seconds, several minutes, or longer depending upon the particular patient and indication.

In still further embodiments, the duty cycle may be varied from the 50% -100% range of values described above, as can

the lengths of the on/off periods. For example, it has been observed that patients can have therapeutic effects (e.g., pain reduction) that persist for significant periods after the stimulation has been halted. In particular examples, the beneficial effects can persist for 10-20 minutes in some cases, and up to an hour in others. Accordingly, the simulator can be programmed to halt stimulation for periods of up to an hour, with appropriate allowances for the time necessary to re-start the beneficial effects. This arrangement can significantly reduce system power consumption, compared to systems with higher duty cycles, and compared to systems that have shorter on/off periods.

Representative Lead Designs

FIG. **16** is a partially schematic illustration of a lead **1610** having first and second contacts C**21**, C**22** positioned in accordance with particular embodiments of the disclosure. The lead **1610** can include at least two first contacts C**21** and at least two second contacts C**22** to support bipolar stimulation via each contact grouping. In one aspect of this embodiment, the lead **1610** can have an overall length L (over which active contacts are positioned) that is longer than that of typical leads. In particular, the length L can be sufficient to position first contacts C**21** at one or more vertebral locations, and position the second contacts C**22** at another vertebral location that is spaced apart from the first and that is superior the first. For example, the first contacts C**21** may be positioned at vertebral levels T9-T12 to treat low back pain, and the second contacts C**22** may be positioned at superior vertebral locations (e.g., cervical locations) to treat arm pain. Pulses may be applied to both groups of contacts in accordance with several different arrangements. For example pulses provided to one group may be interleaved with pulses applied to the other, or the same signal may be rapidly switched from one group to the other. In other embodiments, the signals applied to individual contacts, pairs of contacts, and/or contacts in different groups may be multiplexed in other manners. In any of these embodiments, each of the contacts C**21**, C**22** can have an appropriately selected surface area, e.g., in the range of from about 5 mm^2 to about 20 mm^2, and in particular embodiments, from about 10 mm^2 to about 15 mm^2. Individual contacts on a given lead can have different surface area values, within the foregoing ranges, than neighboring or other contacts of the lead, with values selected depending upon features including the vertebral location of the individual contact.

Another aspect of an embodiment of the lead **1610** shown in FIG. **16** is that the first contacts C**21** can have a significantly wider spacing than is typically associated with standard SCS contacts. For example, the first contacts C**21** can be spaced apart by a distance S**11** that corresponds to between one and two vertebral bodies (typically 32-64 mm.). This increased spacing can reduce the complexity of the lead **1610**, and can still provide effective treatment to the patient because, as discussed above, the effectiveness of the presently disclosed therapy is relatively insensitive to the axial location of the signal delivery contacts. The second contacts C**22** can have a similar wide spacing when used to apply high frequency stimulation in accordance with the presently disclosed methodologies. However, in another embodiment, different portions of the lead **1610** can have contacts that are spaced apart by different distances. For example, if the patient receives high frequency pain suppression treatment via the first contacts C**21** at a first vertebral location, the patient can optionally receive low frequency, paresthesia-inducing signals at the second vertebral location via second contacts C**22** that are spaced apart by a distance S**12**. The distance S**12** can be smaller than the distance S**11** and, in particular embodiments, can be typical of contact spacings for standard SCS treatment, as these contacts may be used for providing such treatment. In still further embodiments, the inferior first contacts C**21** can have the close spacing S**12**, and the superior second contacts C**22** can have the wide spacing S**11**, depending upon patient indications and/or preferences. In still further embodiments, as noted above, contacts at both the inferior and superior locations can have the wide spacing, e.g., to support high frequency stimulation at multiple locations along the spinal cord. In other embodiments, the lead **1610** can include other arrangements of different contact spacings, depending upon the particular patient and indication.

In still further particular embodiments, for example, when the second contacts C**22** are to provide high frequency therapy in the manner of the first contacts C**21**, individual contacts C**22** can be electrically shorted to each other. This can provide benefits including increased field strength and/or reduced signal processing complexity. This system simplification results from the generally robust nature of the applied stimulation, including the ability to avoid current steering, which in turn avoids the need for individually addressable contacts.

In some cases, it may be desirable to adjust the distance between the inferior contacts C**21** and the superior contacts C**22**. For example, the lead **1610** can have a coil arrangement (like a telephone cord) or other length-adjusting feature that allows the practitioner to selectively vary the distance between the sets of contacts. In a particular aspect of this arrangement, the coiled portion of the lead can be located between the first contacts C**21** and the second contacts C**22**. In another embodiment, particularly suitable for the shorted contacts described above, the lead **1610** can be a single or multifilar coil, with selected sections insulated to form contacts at the remaining interstitial locations. This arrangement can be easy to design and manufacture, and can make use of different stencils to provide different contact spacings, depending upon specific patient applications. In addition to or in lieu of the foregoing effect, the coil arrangement can provide for greater maneuverability and facilitate the implantation process by eliminating ring electrodes and/or other rigid contacts. In other embodiments, other arrangements can be used to provide contact flexibility. For example, the contacts can be formed from a conductive silicone, e.g., silicone impregnated with a suitable loading of conductive material, such as platinum, iridium or another noble metal. In still further embodiments, aspects of the coil arrangement can be combined with ring or other types of contacts. For example, the superior portion of the lead **1610** can have a coil arrangement (to support greater flexibility at the distal end of the lead) and the inferior portion of the lead can include ring contacts. In any of these embodiments, the coil portion of the lead can include one or more single and/or multifilar arrangements.

Yet another feature of an embodiment of the lead shown in FIG. **16** is that individual contacts can each have the same current applied to them. For example, as discussed above, each of the contacts can simultaneously receive a cathodic pulse portion and can then each simultaneously receive an anodic pulse portion. In another embodiment, each contact can receive the cathodic pulse portion, and the implanted pulse generator (not visible in FIG. **16**) can serve as a return electrode. For example, the pulse generator can include a housing that serves as the return electrode, of the pulse generator can otherwise carry a return electrode that has a fixed position relative to the pulse generator. Accordingly, the stimulation provided by the active contacts can be unipolar

stimulation, as opposed to the more typical bipolar stimulation associated with standard SCS treatments.

Representative Programmer Designs

The robust characteristics of the presently disclosed therapy techniques may enable other aspects of the overall system described above with reference to FIG. **1**A to be simplified. For example, the patient remote and the physician programmer can be simplified significantly because the need to change stimulation parameters can be reduced significantly or eliminated entirely. In particular, it is expected that in certain embodiments, once the lead is implanted, the patient can receive effective therapy while assuming a wide range of positions and engaging in a wide range of activities, without having to change the signal amplitude or other signal delivery parameters. As a result, the patient remote need not include any programming functions, but can instead include a simple on/off function (e.g., an on/off button or switch). The patient remote may also include an indicator (e.g., a light) that identifies when the pulse generator is active. This feature may be particularly useful in connection with the presently disclosed therapies because the patient will typically not feel a paresthesia, unless the system is configured and programmed to deliberately produce parasthesia in addition to the therapy signal. In particular embodiments, the physician programmer can be simplified in a similar manner, though in some cases, it may be desirable to maintain at least some level of programming ability at the physician programmer. Such a capability can allow the physician to select different contacts and/or other signal delivery parameters in the rare instances when the lead migrates or when the patient undergoes physiological changes (e.g., scarring) or lifestyle changes (e.g., new activities) that are so significant they require a change in the active contact(s) and/or other signal delivery parameters.

Representative Stimulation Locations and Indications

Many of the embodiments described above were described in the context of treating chronic, neuropathic low back pain with stimulation applied to the lower thoracic vertebrae (T9-T12). In other embodiments, stimulation signals having parameters (e.g., frequency, pulse width, amplitude, and/or duty cycle) generally similar to those described above can be applied to other patient locations to address other indications. For example, while the foregoing methodologies included applying stimulation at lateral locations ranging from the spinal cord midline to the DREZ, in other embodiments, the stimulation may be applied to the foramen region, laterally outward from the DREZ. In other embodiments, the stimulation may be applied to other spinal levels of the patient. For example, stimulation may be applied to the sacral region and more particularly, the "horse tail" region at which the sacral nerves enter the sacrum. Urinary incontinence and fecal incontinence represent example indications that are expected to be treatable with stimulation applied at this location. In other embodiments, the stimulation may be applied to other thoracic vertebrae. For example, stimulation may be applied to thoracic vertebrae above T9. In a particular embodiment, stimulation may be applied to the T3-T6 region to treat angina. Stimulation can be applied to high thoracic vertebrae to treat pain associated with shingles. Stimulation may be applied to the cervical vertebrae to address chronic regional pain syndrome and/or total body pain, and may be used to replace neck surgery. Suitable cervical locations include vertebral levels C3-C7, inclusive. In other embodiments, stimulation may be applied to the occipital nerves, for example, to address migraine headaches.

As described above, stimulation in accordance with the foregoing parameters may also be applied to treat acute and/or chronic nociceptive pain. For example, stimulation in accordance with these parameters can be used during surgery to supplement and/or replace anesthetics (e.g., a spinal tap). Such applications may be used for tumor removal, knee surgery, and/or other surgical techniques. Similar techniques may be used with an implanted device to address post-operative pain, and can avoid the need for topical lidocaine. In still further embodiments, stimulation in accordance with the foregoing parameters can be used to address other peripheral nerves. For example, stimulation can be applied directly to peripheral nerves to address phantom limb pain.

From the foregoing, it will be appreciated that specific embodiments of the Invention have been described herein for purposes of illustration, but that various modifications may be made without deviating from the spirit and scope of the invention. Accordingly, the invention is not limited except as by the appended claims.

We claim:

1. A system for managing pain in a patient, using an electrical waveform, comprising:

an electrode device configured to be implanted into a patient and including a plurality of electrodes having at least a first electrode associated with a first area of the patient and a second electrode associated with a second area of the patient, wherein the first area has a first therapy range for a waveform parameter and the second area has a second therapy range for the waveform parameter; and

an implantable device configured to be coupled to the electrode device, the implantable device including a waveform generator configured to generate a non-paresthesia-producing therapy signal, and a computer-operable medium operatively coupled to the waveform generator, the computer-operable medium being programmed to—

direct the non-paresthesia-producing therapy signal to the electrode device with a frequency from 1.5 kHz to 100 kHz;

change a level of a waveform parameter applied to the first electrode; and

automatically set a level of the waveform parameter applied to the second electrode, based on a scaling factor relating the first therapy range to the second therapy range.

2. The system of claim **1** wherein the scaling factor is a ratio of the second therapy range to the first therapy range.

3. The system of claim **1** wherein the therapy ranges are ranges of the waveform parameter that provide a therapeutic effect without inducing discomfort.

4. The system of claim **1** wherein the computer-operable medium is programmed to:

change the waveform parameter applied to the first electrode by a first increment; and

change the waveform parameter applied to the second electrode by a second increment, the second increment being proportional to a ratio of the second therapy range to the first therapy range.

5. The system of claim **1** wherein the computer-operable medium is programmed to receive a plurality of change command inputs, and wherein:

the scaling factor is a ratio of the second therapy range to the first therapy range;

the waveform parameter applied to the first electrode is changed by a first increment for each change command input; and

for each change command input, the waveform parameter applied to the second electrode is set by (a) changing the waveform parameter applied to the second electrode by

the first increment or (b) holding the waveform parameter applied to the second electrode constant.

6. The system of claim **1** wherein the computer-operable medium is programmed to prevent the waveform parameter applied to the first electrode from exceeding a first maximum and prevent the waveform parameter applied to the second electrode from exceeding a second maximum.

7. The system of claim **1** wherein the waveform parameter comprises a waveform amplitude.

8. The system of claim **1** wherein the waveform parameter comprises an impedance between a remote electrode and each of the first electrode at the first area and the second electrode at the second area.

9. The system of claim **1** wherein the waveform parameter comprises waveform power.

10. The system of claim **1** wherein:

the first therapy range corresponds to a difference between (a) a first sensation threshold and/or a first therapeutic threshold and (b) a first discomfort threshold for the first area; and

the second therapy range corresponds to a difference between (a) a second sensation threshold and/or a second therapeutic threshold and (b) a second discomfort threshold for the second area.

11. The system of claim **1** wherein the computer-operable medium is programmed to:

store diagnostics including a plurality of observed patient usage patterns; and

transmit the diagnostics of observed patient usage patterns to a remote processor that determines the first therapy range, the second therapy range, and a ratio of the second therapy range to the first therapy range.

12. The system of claim **1** wherein the computer-operable medium is programmed to:

determine a first ratio of the second therapy range to the first therapy range associated with a first patient position;

determine a second ratio of the second therapy range to the first therapy range associated with a second patient position; and

change the waveform parameter applied to the first and second electrodes based on the first ratio when the patient is in the first position or based on the second ratio when the patient is in the second position.

13. The system of claim **1** wherein the computer-operable medium is programmed to:

receive a first maximum for the waveform parameter applied to the first electrode and set a second maximum for the waveform parameter applied to the second electrode; and

decouple the second electrode from the first electrode for adjustment of the parameter when one of the first or second electrodes has reached the first or second maximum, respectively.

14. The system of claim **1** wherein the computer-operable medium is programmed to:

change the waveform parameter applied to the first electrode by a first increment; and

change the waveform parameter applied to the second electrode by a second increment, wherein the second increment is the product of the first increment and a ratio of the second therapy range to the first therapy range.

15. A spinal cord modulation system, comprising:

a signal delivery device having a proximal portion and a distal portion, wherein the distal portion includes a plurality of electrodes having at least a first electrode associated with a first area of the patient and a second electrode associated with a second area of the patient, wherein the first area has a first therapy range for a waveform parameter and the second area has a second therapy range for the waveform parameter; and

a pulse generator coupleable to the proximal portion of the signal delivery device and programmed with instructions that, when executed:

generate and transmit to the signal delivery device a non-paresthesia-producing therapy signal having a frequency in a frequency range of 1.5 kHz to 100 kHz;

change a level of a waveform parameter applied to the first electrode; and

automatically set a level of the waveform parameter applied to the second electrode, based on a relationship between the first therapy range and the second therapy range.

16. The system of claim **15** wherein the relationship includes a scaling factor relating the first therapy range to the second therapy range.

17. The system of claim **16** wherein the scaling factor is a ratio of the second therapy range to the first therapy range.

18. The system of claim **15** wherein the therapy signal has an amplitude between 0.1 mA and 20 mA.

19. The system of claim **15** wherein the therapy signal has a plurality of biphasic pulses having a pulse width between 10 microseconds and 333 microseconds.

20. The system of claim **15**, wherein the pulse generator is an implantable pulse generator.

21. The system of claim **15**, wherein the pulse generator is an external pulse generator.

22. The system of claim **15**, wherein the signal delivery device includes an elongated lead.

23. The system of claim **15**, wherein the signal delivery device includes a paddle lead.

24. The system of claim **15** wherein the pulse generator is programmed to:

change the waveform parameter applied to the first electrode by a first increment; and

change the waveform parameter applied to the second electrode by a second increment, the second increment being proportional to a ratio of the second therapy range to the first therapy range.

25. The system of claim **15** wherein the pulse generator is programmed to receive a plurality of change command inputs, and wherein:

the scaling factor is a ratio of the second therapy range to the first therapy range;

the waveform parameter applied to the first electrode is changed by a first increment for each change command input; and

for each change command input, the waveform parameter applied to the second electrode is set by (a) changing the waveform parameter applied to the second electrode by the first increment or (b) holding the waveform parameter applied to the second electrode constant.

26. The system of claim **15** wherein the pulse generator is programmed to prevent the waveform parameter applied to the first electrode from exceeding a first maximum and prevent the waveform parameter applied to the second electrode from exceeding a second maximum.

27. The system of claim **15** wherein the waveform parameter comprises a waveform amplitude.

28. The system of claim **15** wherein the waveform parameter comprises an impedance between a remote electrode and each of the first electrode at the first area and the second electrode at the second area.

29. The system of claim 15 wherein the waveform parameter comprises waveform power.

30. The system of claim 15 wherein:

the first therapy range corresponds to a difference between (a) a first sensation threshold and/or a first therapeutic threshold and (b) a first discomfort threshold for the first area; and

the second therapy range corresponds to a difference between (a) a second sensation threshold and/or a second therapeutic threshold and (b) a second discomfort threshold for the second area.

31. The system of claim 15 wherein the pulse generator is programmed to:

store diagnostics including a plurality of observed patient usage patterns; and

transmit the diagnostics of observed patient usage patterns to a remote processor that determines the first therapy range, the second therapy range, and a ratio of the second therapy range to the first therapy range.

32. The system of claim 15 wherein the pulse generator is programmed to:

determine a first ratio of the second therapy range to the first therapy range associated with a first patient position;

determine a second ratio of the second therapy range to the first therapy range associated with a second patient position; and

change the waveform parameter applied to the first and second electrodes based on the first ratio when the patient is in the first position or based on the second ratio when the patient is in the second position.

33. The system of claim 15 wherein the pulse generator is programmed to:

receive a first maximum for the waveform parameter applied to the first electrode and set a second maximum for the waveform parameter applied to the second electrode; and

decouple the second electrode from the first electrode for adjustment of the parameter when one of the first or second electrodes has reached the first or second maximum, respectively.

34. The system of claim 15 wherein the pulse generator is programmed to:

change the waveform parameter applied to the first electrode by a first increment; and

change the waveform parameter applied to the second electrode by a second increment, wherein the second increment is the product of the first increment and a ratio of the second therapy range to the first therapy range.

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